UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Prevention, Pesticides
and
Toxic Substances

July 30, 2002

SUBJECT: Carbaryl: Revised HED Risk Assessment - Public Comment Period, Error Correction Comments Incorporated, DP Barcode: D284580, PC Code: 056801

FROM: Jeffrey L. Dawson, Chemist/Risk Assessor
Reregistration Branch 1
Health Effects Division (7509C)

THRU: Whang Phang, PhD, Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

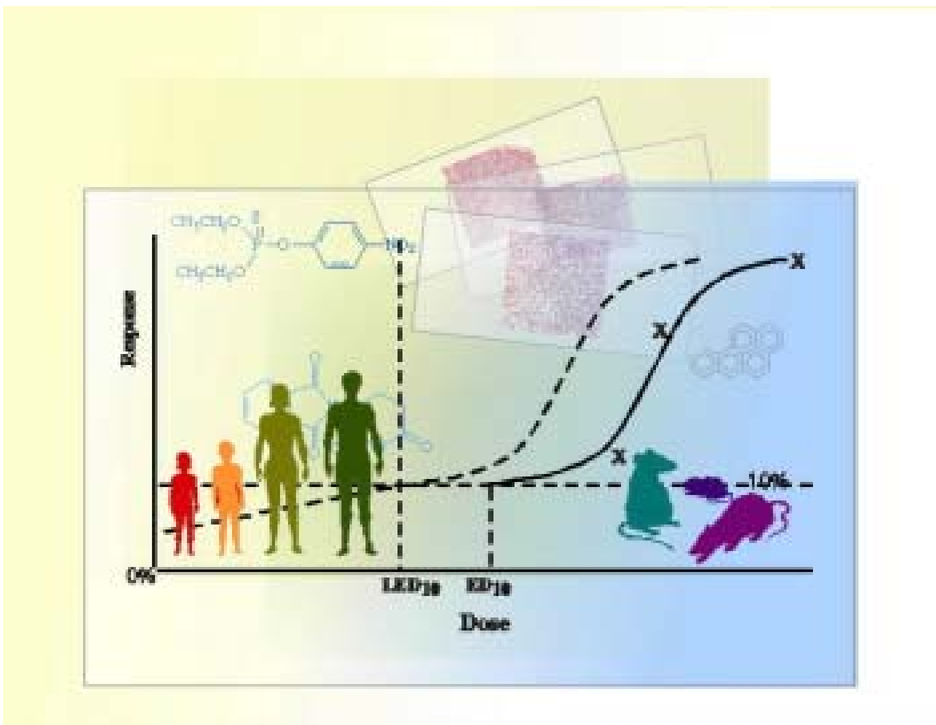
TO: Anthony Britten, Chemical Review Manager
Reregistration Branch 3
Special Review & Reregistration Division (7508C)

Attached is HED's risk assessment of the insecticide carbaryl for purposes of issuing a Reregistration Eligibility Decision (RED) Document for this active ingredient. This document is based on several disciplinary science chapters which include: Toxicology - D282980; Dietary Exposure - D281419; Product and Residue Chemistry - D283328; Occupational and Residential Exposure - D281418; and Estimated Environmental Concentrations - D240841. This chapter reflects recent changes in the hazard component based on the submission of additional toxicology studies (reproductive and three 21-day dermal toxicity studies); changes in endpoint selection; revision of the Q_1* for cancer risk assessment; and a reduction in the FQPA SF from 10 to 1. Modifications to the occupational and residential assessment includes changes in the calculations for pet uses; the use of recently submitted ARTF transfer coefficients for greenhouse crops; and changes to the updated duration policy for delineating short- and intermediate-term exposures. Also, mosquito adulticide and carbaryl use on oyster beds in Washington state have been quantitatively addressed. Modifications to the dietary risk assessment include: the use of updated processing factors; deletion of some use patterns; and the use of additional residue data. This document also addresses error correction comments raised by Aventis Crop Sciences included in the document *Human Health Risk Assessment and Supporting Documents - Phase 1 Error Correction* (July 12, 2002) that were submitted on the previous version of this assessment (D281420, Dated June 7, 2002).

Reviewers: RARC (6/6/01 Report), Revision (6/7/02) Reviewed By Paula Deschamp

HUMAN HEALTH
RISK ASSESSMENT

Carbaryl



U.S. Environmental Protection Agency
Office of Pesticide Programs
Health Effects Division (7509C)
Jeffrey L. Dawson, Chemist/Risk Assessor

Date: July 30, 2002

HUMAN HEALTH RISK ASSESSMENT

Carbaryl

Risk Assessment Team:

Risk Assessor:	**Jeffrey L. Dawson,**
Dietary Risk:	**Felecia Fort**
Product and Residue Chemistry:	**Felecia Fort**
Occupational and Residential Exposure:	**Jeffrey L. Dawson**
Epidemiology:	**Jerome Blondell, MPH, PhD** **Monica Spann, MPH** **Virginia Dobozy, VMD, MPH**
Toxicology:	**Virginia Dobozy, VMD, MPH**
Drinking Water Estimates:	**R. David Jones, Ph.D.** **E. Laurence Libelo, Ph.D.**

Table of Contents

1.0 EXECUTIVE SUMMARY 5

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION 17
2.1 Chemical Structure and Identification 17
2.2 Physical Properties of Carbaryl 18

3.0 HAZARD CHARACTERIZATION 19
3.1 Hazard Profile 19
3.2 FQPA Considerations 22
3.2.1 Determination of Susceptibility 22
3.2.2 Degree of Concern Analysis and Residual Uncertainties 23
3.3 Dose Response Assessment 24
3.4 Endocrine Disruption 26

4.0 NON-OCCUPATIONAL RISK ASSESSMENT AND CHARACTERIZATION 27
4.1 Summary of Registered Uses 27
4.2 Dietary Risk Assessment 31
4.2.1 Residue Profile 32
4.2.2 Acute Dietary Risk Assessment 34
4.2.3 Chronic Dietary Risk Assessment 37
4.2.4 Cancer Dietary Risk Assessment 38
4.2.5 Characterization/Uncertainties of the Dietary Risk Estimates 38
4.3 Estimated Environmental Concentrations In Water 39
4.3.1 Environmental Fate Characteristics 39
4.3.2 Monitoring Data 40
4.3.3 Modeling EECs 41
4.4 Residential Risk Assessment 43
4.4.1 Home Uses 44
4.4.2 Residential Handler Risk Assessment 44
4.4.2.1 Residential Handler Noncancer Risks 47
4.4.2.2 Residential Handler Cancer Risks 51
4.4.3 Residential Postapplication Risk Assessment 54
4.4.3.1 Residential Postapplication Exposure and Noncancer Risks 59
4.4.3.2 Residential Postapplication Exposure and Risks For Cancer 65
4.4.4 Residential Risk Characterization 66
4.4.5 Exposure from the Use of Tobacco 69
4.4.6 Other Residential Exposures 69

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION 70
5.1 Calculation of Aggregate Risks and DWLOCs 70
5.2 Acute Dietary Aggregate Risks and DWLOCs 73
5.3 Chronic Dietary Aggregate Risks and DWLOCs 73
5.4 Short-term Aggregate Risks and DWLOCs 74
5.5 Intermediate-term Aggregate Risks and DWLOCs 75
5.6 Aggregate Cancer Risks and DWLOCs 76
5.7 Summary of Aggregate Risks 77

6.0 CUMULATIVE RISK 78

7.0 OCCUPATIONAL RISK ASSESSMENT 79
7.1 Occupational Handler Risk Assessment 79
7.1.1 Occupational Handler Non-Cancer Risks 84
7.1.2 Occupational Handler Cancer Risks 88
7.2 Postapplication Exposures and Risks 92
7.2.1 Occupational Postapplication Noncancer Risks 95
7.2.2 Occupational Postapplication Exposure and Risk Estimates for Cancer 98
7.3 Occupational Risk Characterization 101

8.0 HUMAN AND DOMESTIC ANIMAL INCIDENT DATA REVIEW 104

9.0 DATA NEEDS 105

APPENDIX 1: Toxicology Profile

APPENDIX 2: Incident Review

1.0 EXECUTIVE SUMMARY

The Health Effects Division (HED) of EPA's Office of Pesticide Programs has evaluated the carbaryl database and conducted a human health risk assessment for the reregistration of the chemical. Carbaryl is a list A reregistration chemical. Carbaryl is also subject to court specified deadlines resulting from a Natural Resources Defense Council (NRDC) petition of the Agency. This assessment incorporates error corrections and begins phase 3 of the public participation process.

Use Patterns:

Carbaryl [1-napthyl methylcarbamate] is one of the most widely used broadspectrum insecticides in agriculture, professional turf management, professional ornamental production, and in the residential pet, lawn and garden markets. Carbaryl formulations include baits, dusts, pet collars, flowable concentrates, emulsifiable concentrates, granulars, soluble concentrates, and wettable powders. Carbaryl is used in agriculture to control pests on terrestrial food crops including fruit and nut trees (e.g., apples, pears, almonds, walnuts, and citrus), many types of fruit and vegetables (e.g., cucumbers, tomatoes, lettuce, blackberries, and grapes), and grain crops (e.g., corn, rice, sorghum, and wheat). Carbaryl is also used for direct animal treatments to control pests on companion animals such as dogs and cats. There are other uses for ornamentals and turf, including production facilities such as greenhouses, golf courses, and residential sites that can be treated by professional applicators (e.g., annuals, perennials, shrubs). Carbaryl can also be used by homeowners on lawns, for home and garden uses, and on companion animals. There are no labels for indoor uses within a residence. In agriculture, groundboom, airblast, and aerial applications are typical. Other applications can also be made using handheld equipment such as low pressure handwand sprayers, backpack sprayers, and turfguns. Homeowners can also use other types of application equipment including trigger sprayers, hose-end sprayers, and ready-to-use dust packaging. Information on uses and application rates used in the risk assessment was provided by the registrant, Aventis Crop Science, at a SMART meeting on September 21, 1998 and from a review of current labels. The Agency's Biological and Economic Analysis Division has also concurred with the use patterns which serve as the basis for this assessment. Carbaryl also has more specialized uses that can lead to exposures in the general population such as an adulticide for mosquito control and for Ghost and Mud shrimp control in oyster beds in Washington State. These use patterns were also considered in this assessment.

Hazard Characterization:

Carbaryl is a carbamate insecticide where the mode of toxic action is through cholinesterase inhibition (ChEI). In most of the toxicology studies in which ChEI activity was measured, it was the endpoint used for setting the No Observed Adverse Effect Level (NOAEL) for risk assessment, the dose at which no adverse effects were observed. There was one exception; for chronic duration exposures, a NOAEL could not be defined in the toxicology study deemed most appropriate (i.e., chronic dog toxicity) so a Lowest Observed Adverse Effect Level (LOAEL), the dose at which the first adverse effects were observed, was used for risk assessment purposes. Carbaryl is relatively acutely toxic by the oral route (Toxicity Category II) but has relatively low acute toxicity by the dermal and inhalation routes. It is not a dermal or eye irritant or a dermal sensitizer; however, there are reports of dermal irritation and dermal manifestations of an allergic response in humans exposed to carbaryl.

The Agency is required by the Food Quality Protection Act to consider the special sensitivities of various susceptible populations such as infants and children. Current Agency policy retains the factor using criteria based on exposure and toxicity considerations. For carbaryl, a traditional factor of 3 was applied only to chronic duration exposures to account for the lack of a NOAEL in the selected chronic dog toxicity study (i.e., the use of a LOAEL). The Agency decided that the special FQPA Safety Factor should be reduced to 1 and that this was adequate to protect susceptible populations because there are no residual uncertainties in the exposure databases, the toxicology database is complete, and the endpoint and NOAELs for risk assessment were well defined. Dietary exposures were calculated using FDA and PDP monitoring data, a carbamate market basket survey, and percent crop treated information. Residential exposures were calculated using a number of carbaryl-specific studies. In the toxicology database, no quantitative or qualitative evidence of increased susceptibility in rat or rabbit fetuses following *in utero* exposure in the standard developmental studies was observed. There was a low level of concern for evidence of susceptibility seen in the developmental neurotoxicity study, and there was evidence of increased susceptibility in offspring in the 2-generation reproduction study. However, the Agency believes that the acute and chronic RfDs would be protective of these effects so the special FQPA safety factor was reduced to 1.

Carbaryl has been classified as a Group C possible human carcinogen based on an increased incidence of hemangiosarcomas and combined hemangiomas/hemangiosarcomas in CD-1 mice at 100 ppm and above (15 and 18 mg/kg/day for males and females, respectively). Mechanistic metabolism studies and a study in heterozygous p53-deficient mice were considered inadequate to demonstrate a mode of action for the vascular tumors. Therefore, a linear low dose extrapolation approach was used for risk assessment; the Q_1* is 8.75 x 10^{-4} $(mg/kg/day)^{-1}$ based on the mouse vascular tumors according to the February 2002 Cancer Assessment Review Committee (CARC) report. Also, CARC concluded that there is a concern for mutagenicity because carbaryl has been observed to be clastogenic *in vitro*. However, this concern is lessened because of a lack of effects observed *in vivo* (i.e., micronuclei induction and chromosome aberration studies were negative).

Endpoints for acute and chronic dietary exposure risk assessments were selected by the HED Hazard Identification Assessment Review Committee (HIARC). The toxicity endpoints selected for risk assessment are neurotoxic effects associated with the inhibition of ChEI. The dose level used for the acute dietary risk assessment was a NOAEL which was defined in a developmental neurotoxicity study conducted with rats (1 mg/kg/day). The dose level used for the chronic dietary risk assessment was a LOAEL which was defined in a chronic dog feeding study (3.1 mg/kg/day). Because a NOAEL could not be defined in the chronic study, an additional factor of 3x was added to the customary 100x factor (i.e.,10x for extrapolation from animal studies to humans and 10x for intraspecies variation between the test animals and humans) to account for the uncertainty associated with a lack of a NOAEL. The acute and chronic reference doses (RfD) were 0.01 mg/kg/day (i.e., dose/100 for acute and dose/300 for chronic). The Population Adjusted Dose (PAD) is a modification of the acute or chronic RfD to accommodate the FQPA safety factor and is calculated by dividing the RfD by the FQPA safety factor. The PADs are the values used for the acute and chronic dietary risk calculations. The Special FQPA Safety Factor was reduced to 1 as described above. Therefore, the aPAD and cPAD (i.e., PAD values for acute and chronic dietary exposures, respectively) are both 0.01 mg/kg/day.

There are many potential ways people can be exposed to carbaryl in occupational and residential settings. The Agency considers exposures for those involved in the application of carbaryl (i.e., handlers) and those who can come into contact with carbaryl residues after application (i.e., reentry or postapplication). Both cancer and non-cancer risk assessments were conducted for residential handlers and for people in the general population who might be exposed postapplication from lawn, garden, or pet uses of carbaryl or from more specialized uses such as mosquito adulticide applications and uses on oyster beds in Washington state. Similarly, both handler and postapplication risks were calculated for those people who could be exposed as part of their jobs such as a grower treating their crop or someone harvesting fruit. Endpoints for occupational and residential exposures from various routes (i.e., dermal, inhalation, and incidental oral) and differing durations (i.e., short-term, intermediate-term, and chronic) were selected by the HIARC. Based on current policy, short-term exposure was defined as 1 to 30 days, intermediate-term exposures as 30 days to several months, and chronic exposures as several months to a lifetime. [Note: Not all routes and durations are applicable to each population.] The toxicity endpoints selected for these carbaryl risk assessments are again based on neurotoxic effects associated with the inhibition of ChEI. The short- and intermediate-term dermal risk assessments for carbaryl are based on NOAEL of 20 mg/kg/day defined in a dermal toxicity study in rats using technical material where decreases in red blood cell cholinesterase in males and females and brain cholinesterase in males were observed. The short-term inhalation and nondietary ingestion risk assessments for carbaryl are based on a NOAEL of 1 mg/kg/day which was defined in a developmental neurotoxicity study in rats where alterations in FOB measurements and cholinesterase inhibition (plasma, whole blood, and brain) were observed. The intermediate-term inhalation and nondietary ingestion risk assessments are based on a NOAEL of 1 mg/kg/day that was defined in a subchronic neurotoxicity study in rats. The chronic risk assessments, regardless of how exposures occur (e.g., skin or inhaled) are based on a LOAEL of 3.1 mg/kg/day that was defined in a 1 year dog feeding study. In some assessments, a dermal absorption factor is required. A rat dermal absorption study using radiolabeled ^{14}C carbaryl was used to define a factor of 12.7 percent; this value was used to calculate the oral equivalent dermal dose for noncancer chronic duration exposures and for the calculation of cancer risks. No inhalation toxicity studies were available for risk assessment purposes so a route-to-route extrapolation was used to address risks from inhalation exposures. No inhalation absorption study was conducted; therefore, a 100 percent inhalation absorption factor has been used to convert all inhalation exposures to an oral equivalent inhalation dose.

Dietary Risk Estimates:

Potential dietary exposure to carbaryl occurs through food and water. Tolerances for residues of carbaryl are currently expressed in terms of carbaryl and its hydrolysis product, 1-naphthol (calculated as carbaryl) for most raw agricultural commodities. However, HED is recommending that carbaryl *per se* be regulated in plants. In livestock commodities, carbaryl; 5,6-dihydro-5,6-dihydroxy carbaryl; and

5-methoxy-6-hydroxy carbaryl and all residues which can be hydrolyzed to carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, or 5-methoxy-6-hydroxy carbaryl under acidic conditions should be included in the tolerance expression and risk assessment for all endpoints of dietary concern. Once the tolerances for plants are revised, they will be compatible with Codex MRLs except for livestock commodities.

A Tier 3/4 dietary risk assessment, which is the most highly refined assessment possible at this time, was conducted. Both acute and chronic dietary risk assessments were conducted. Dietary exposure was determined, considering the level of carbaryl residue on food commodities and their potential consumption by multiple subpopulations. Dietary risk was then calculated by comparing dietary exposure to the acute or chronic PADs. Data on anticipated carbaryl residues were determined based mainly on USDA Pesticide Data Program (PDP) and Food and Drug Administration (FDA) monitoring data. Field trial data were used for certain commodities. In addition, separate acute assessments were conducted incorporating the results of the Carbamate Market Basket Survey (CMBS).[1] The percentage of the crop treated (estimated maximum percentage and weighted average percentage for the acute and chronic analyses, respectively) was also considered. Food consumption data were from 2 of USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) which ranged from 1989 to 1992 and from 1994 to 1998. The 1994 to 1998 data were included based on comments from the registrant, Aventis Crop Science, for comparative purposes (1989 to 1992 are normally used for risk assessment). In these surveys, 3-day mean consumption and single-day consumption information were recorded for 22 demographic and socio-economic subpopulations, including infants, children, and nursing women. Dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM™), which incorporates exposure and consumption data to calculate risk as a percentage of the PAD. Values greater than 100 percent of the PAD exceed HED's level of concern.

Estimated acute dietary exposure for carbaryl at the 99.9th percentile using the 1989 to 1992 CFSII data exceeds HED's level of concern for some population subgroups when CMBS data are not used and are not of concern when the CMBS are incorporated. The results of the acute dietary assessment when CMBS data have not been used indicate risks are greater than 100 percent of the aPAD for all infants (<1 year old) and children (1-6 years old) at the 99.9th percentile of exposure (133 % and 110% of aPAD, respectively). When CMBS data were incorporated, the highest exposed subpopulation was children (1-6 years old) at 75 percent of the aPAD. A sensitivity analysis was completed by the Agency (not using the CMBS) to evaluate the impacts of eliminating apples or peaches from the analysis and eliminating commodities with no detectable residues. Eliminating peaches appears to have the most impact as all infants in this analysis consume 72 percent of the aPAD but children (1-6 years old) still consume just over 100 percent of the aPAD (i.e., 102 percent). One comment from Aventis Crop Science was that 1994 to 1998 CFSII food consumption data should be used rather than 1989 to 1992 data. Results for most subpopulations were actually slightly worse (i.e., generally, 5 to 10 percent

---

[1] At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. The primary concern was rubbing sampled commodities during the rinsing process except for broccoli and tomato because this created a potential for residue loss from the mechanical action associated with rubbing. A separate assessment was also completed using other sources of high quality residue data (e.g., PDP) for comparative purposes to more completely inform the risk management process.

more of the aPAD was consumed) if the 1994 to 1998 CFSII data were used.

Estimated chronic dietary risks for all population subgroups are not of concern. Estimated chronic dietary exposures for all population subgroups consumed <1 percent of the cPAD. The CMBS data were not used in this analysis because risks are low and CMBS is single serving data.

The cancer dietary exposure assessment was conducted using the Q_1* approach (i.e., linear, low dose extrapolation). Dietary exposure is determined from consumption and residue data, as was done for the acute and chronic dietary assessments. The food exposure is then multiplied by the Q_1* (8.75×10^{-4}) $(mg/kg/day)^{-1}$ for carbaryl to determine the increased risk of cancer from consuming carbaryl residues in food over a lifetime (70 years). Risks estimates above 1×10^{-6} are of concern. Results indicate a maximum lifetime risk of 2.8×10^{-8} for the general US population.

Concentrations in Water:

Monitoring data for carbaryl residues in ground and surface water are available, but they are of limited utility in developing estimated environmental concentrations (EECs) for the aggregate dietary (food and water) risk assessment. Therefore, computer modeling was used to estimate surface (PRZM 3.12 and EXAMS 2.97.7) and ground (SCI-GROW) water concentrations expected from normal agricultural use. These model estimates were compared to drinking water levels of concern (DWLOCs), the theoretical concentration of pesticide in drinking water that would be an acceptable upper limit in light of the aggregate exposure to that pesticide from other sources (food and residential use). The maximum calculated acute and chronic surface water EECs (494 ppb and 28 ppb, respectively) resulted from use on citrus in Florida. In Florida, the majority of drinking water is derived from groundwater (>90%) so high surface water concentrations do not necessarily indicate high exposure. As a result, both Florida and the results for Oregon apples (the next highest EECs) have been considered in the aggregate assessment (144 and 9 ppb for acute and chronic, respectively). Groundwater EECs for the acute and chronic assessments were both 0.8 ppb as calculated with SCI-GROW.

Use of Consumer Products (Residential Handlers):

The noncancer risks of short-term dermal and inhalation exposure to residential handlers were calculated using Margins of Exposure (MOEs) in which the doses were selected from the 21-day dermal toxicology study using technical material and the developmental neurotoxicity study, respectively. The target (acceptable) MOE for residential short-term risk assessments is 100 based on the customary 100x uncertainty factor (i.e., 10x for inter- and 10x for intra-species) and the FQPA Safety Factor of 1. Calculated MOEs that equal or exceed the target MOE of 100 are not of concern. Combined (dermal and inhalation) risks were calculated for 17 scenarios (i.e., 52 site/area/rate combinations within those scenarios) considered representative of the residential uses, application rates and application equipment on carbaryl labels. For residential handlers, MOEs associated with most (40 of 52 considered) are generally not of concern because they exceed the Agency's target MOEs for noncancer risk assessments (i.e., MOE = 100). The scenarios of concern involve the use of dusts (in gardens and on pets) and for some liquid sprays on gardens.

The risk of cancer in residential handlers was calculated considering one application of carbaryl per year for 50 years. The annual frequency for use was reported to be 1 to 2 times per year (60^{th} percentile) and 5 times per year (84^{th} percentile) by the registrant, the Aventis Crop Science, at the SMART meeting held with the Agency. Risks were calculated by multiplying the Lifetime Average Daily Dose (LADD), which represents dermal and inhalation exposure amortized over a lifetime, by the Q_1*. The risk considered acceptable is 1×10^{-6}, which means that an individual receiving a lifetime exposure to a pesticide increases their chance of developing cancer by one in a million. Based on a single day of exposure, cancer risks for most scenarios are in the 10^{-8} to 10^{-10} range although there is one scenario where the risk exceeds $1x10^{-6}$ (dusting dogs) even for a single day of use. Cancer risks have also been calculated using another approach where the number of days per year of exposure required to exceed a risk of $1x10^{-6}$ has been defined. There are 5 scenarios where the allowable days per year of exposure is less than or equal to 5 which should be considered in conjunction with the use/usage data from Aventis Crop Science that indicates 5 uses per year is the 84^{th} percentile. In all cases, cancer risk estimates require less restrictive risk mitigation measures than do the corresponding results for noncancer concerns (i.e., noncancer risks appear to be driving the need for risk mitigation).

Residential Postapplication Exposures:

HED considered a number of residential postapplication exposure scenarios for toddlers, youth-aged children and adults. Short-term and intermediate-term risks from declining residues were calculated for multiple scenarios, including exposures to treated lawns (toddlers and adults), golf courses (adults), gardens (adults and youth-aged children) and pets (toddlers). Exposures from more limited uses such as a mosquito adulticide and for use in oyster beds were also considered. Short- and intermediate-term dermal risks were calculated using the NOAEL from the 21-day dermal toxicity study (i.e., 20 mg/kg/day). Risks from short- and intermediate-term nondietary ingestion (e.g., mouthing behaviors) were calculated using NOAELs from the developmental neurotoxicity study in rats and the subchronic neurotoxicity study in rats where the NOAELs both happen to be 1 mg/kg/day. The target MOE is also 100 for all scenarios considered. MOEs were calculated over the amount of time it took residues to dissipate or out to a 30 day interval whichever applied depending upon the data. Short-term MOEs were calculated based on the residue concentrations for each day while intermediate-term risks were calculated using a 30 day average. The Agency has short-term risk concerns for exposures to adults doing heavy yardwork, for toddlers playing on treated lawns, and for toddlers that have contact with treated pets. Activities associated with home gardening (e.g., harvesting) and golfing for adults, home gardening for youth-aged children or any age or activity considered in the adulticide mosquito control or oyster assessment do not have risk concerns even on the day of application (i.e., MOEs $\geq$100 on the day of application). For adults, the MOEs for heavy yardwork do not meet or exceed risk targets (i.e., MOE $\geq$ 100) up to 5 days after application. For toddlers, the Agency has concerns for pet treatments and also for lawn uses. In fact, pet uses never reach acceptable levels even 30 days after application and not until 18 days at the maximum application rate considered on turf. Toddler MOEs from pet and turf uses represent total exposures from multiple pathways. For the pet uses, dermal and hand-to-mouth exposures essentially both equally contribute to the overall estimate. For the turf uses, dermal and hand-to-mouth exposures are also the key contributors to the overall estimates. The Agency does not have intermediate-term risk concerns for adults and youth-aged children for any of the uses considered including lawncare, home gardens, golfing, and any aspect of adulticide mosquito control or uses in oyster beds. In contrast, the Agency does have intermediate-term risk concerns for all toddler exposure scenarios considered (i.e., pet treatments and lawncare uses). As with the short-term MOEs, pet and turf uses represent total exposures where the significant contributions to overall exposures are again made equally from the dermal and hand-to-mouth exposure pathways.

Ingestion of carbaryl granules is also a potential source of exposure because children can eat them if they are found in treated lawns or gardens. This scenario is considered episodic by the Agency and is generally not recommended as a basis for risk management decisions. For illustrative purposes, if one considers a 2 percent formulation and the density of soil (0.67 mL/gram, many granulars are claybased), only 0.005 mL of formulation would need to be ingested to have a risk concern (i.e., 7.5 mg * 1g/1000mg * 0.67 mL/gram). [Note: This volume is orders of magnitude less than a teaspoon of granular formulation (i.e., 0.1% of a teaspoon where a tsp. = 5 mL).]

Use in Tobacco:

In addition to the routine residential risk assessment, HED calculated the risks of carbaryl exposure in tobacco because a pyrolysis study was submitted by the registrant that quantified residues of carbaryl at a level of 44.58 ppm in tobacco smoke (side-stream and main-stream combined). Since this is a composited sample of main-stream and side-stream smoke, it greatly exaggerates the actual exposure to the smoker, whose primary route of exposure is via main-stream smoke. HED further assumed that 100 percent inhaled is absorbed (i.e., that none of the residue is exhaled along with the smoke). The MOE for consuming 15 cigarettes per day is 104 even with the conservative basis of the assessment.

Aggregate Risks and DWLOCs:

The Food Quality Protection Act requires that the Agency consider exposures from different sources (i.e., food water, and residential) that results in an aggregate risk for each chemical. Aggregate risks are calculated by considering food or food and residential (depends upon the specific scenario), subtracting these from the allowable exposure limit, and, if the exposure limit has not been exceeded, then calculating Drinking Water Levels of Concern (DWLOCs) to compare to surface or groundwater Estimated Environmental Concentrations (EECs). In many residential scenarios, MOEs exceed the Agency's risk targets making the calculation of DWLOCs and aggregate risks for those scenarios inappropriate because the allowable exposure limits have already been exceeded. Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment (133 % of aPAD). However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency, and the Agency uses the CMBS data even with the caveats associated with that study. Keeping this in mind, the Agency completed DWLOC and aggregate risk calculations for illustrative purposes using a number of representative exposure scenarios where the residential and dietary risk estimates did not already exceed the Agency's level of concern. For example, an acute assessment with CMBS data and short-term assessments where residential handler risks weren't already of concern were completed.

The acute aggregate assessment indicates that even with the use of the CMBS, aggregate risks when surface water is the source of drinking water, are still of concern for all infants, children (1 to 6 years old) and children (7 to 12 years old) regardless of whether or not Florida citrus or Oregon apple EECs are used. If Florida citrus surface water EECs are solely considered, aggregate risks are of concern for all subpopulations. [Note: For characterization of the EECs, surface water EECs for Florida citrus exceed exposure limits alone without even considering corresponding food intakes for all populations. Additionally, the surface water EECs for Oregon apples alone also exceed exposure limits, even without including food intakes, for infants and children.] Acute aggregate risks for all subpopulations are not of concern if groundwater is the source of drinking water. Chronic aggregate risks were not of concern for any subpopulation regardless of the source of drinking water, even considering the Florida surface water EECs. In the short-term assessment, the Agency selected representative scenarios where residential risks alone were not of concern including mosquito control, oyster harvesting, golfing, garden harvest, and several handler scenarios (handlers all at average rates, max rate scenarios were of concern for residential exposures alone). If surface water EECs based on Oregon apples or groundwater EECs from SciGrow are considered, aggregate risks are not of concern for the selected scenarios. If EECs from Florida citrus are considered, aggregate risks are not of concern for the selected scenarios except for application of dusts to gardens. Separate intermediate-term aggregate risk and DWLOC calculations were not completed for carbaryl because the short-term aggregate risk estimates essentially present the same results since the hazard inputs are numerically identical. The only major differences would be the postapplication results where, instead of a single day exposure estimate, the exposures represent a 30 day average (i.e., risks would be accordingly lower since an average rather than a single high end day was considered). Aggregate cancer risks were not of concern for any subpopulation regardless of the source of drinking water, even considering the Florida surface water EECs.

Cumulative Risks:

Carbaryl is a member of the carbamate class of pesticides. This class also includes the aldicarb, methomyl and oxamyl among others. HED did not perform a cumulative risk assessment as part of this reregistration review for carbaryl because HED has not yet initiated a review to determine if there are any other chemical substances that have a mechanism of toxicity common with that of carbaryl. For purposes of this reregistration decision, EPA has assumed that carbaryl does not have a common mechanism of toxicity with other substances.

Occupational Handlers:

There is significant potential for exposure to carbaryl users in a variety of agricultural and commercial settings. Tasks associated with occupational carbaryl use include mixing, loading and applying the chemical or guiding aerial applications (flaggers). All these activities are collectively referred to as handler tasks. A total of 28 scenarios were considered representative of the range of handler activities, crops or acres treated and equipment used. The risks from short- and intermediate-term dermal exposures and short- and intermediate-term inhalation exposures in these scenarios were calculated and then added together to obtain overall risk estimates at varying levels of personal protection. The target MOEs were 100 for short-term and intermediate-term exposures. [Note: Does not include FQPA Safety Factors as they are not applicable to occupational exposures.] Risks from long-term (chronic) exposures were also calculated for a limited number of scenarios in the ornamental/greenhouse industry. The short- and intermediate-term risk assessments were conducted, as described above. The long-term risk assessment for carbaryl was based on a 1 year dog feeding study where effects (ChEI) were observed at 3.1 mg/kg/day (LOAEL). The target MOE was 300 (customary 100x plus 3x for use of LOAEL). Risks were calculated assuming one of eight possible levels of personal protection equipment, ranging from a baseline of typical work clothing (long-sleeved shirt and long pants, no respiratory protection and no chemical-resistant gloves) to engineering controls, such as a closed cab or closed loading system. Current carbaryl labels typically require that handlers wear long pants, long-sleeved shirts, and gloves but do not require respirators. For most scenarios, the noncancer risks for this personal protection ensemble do not meet Agency risk requirements and additional levels of personal protection are required to achieve Agency risk targets. In fact, in many cases engineering controls such as closed loading systems or closed cab tractors are needed. The Agency does have risk concerns over the use of carbaryl in some agricultural and other occupational settings regardless of the level of personal protection used (i.e., MOEs at any level of personal protection are <targets). As would be expected, these scenarios with the highest associated risk also have high daily chemical use amounts based on application rates or high acreages treated or the exposures for the scenarios in question are relatively high. Generally, the areas that appear to be problematic include: large acreage aerial and chemigation applications in agriculture or for wide area treatments such as mosquito control; airblast applications at higher rates; pet grooming; and the use of certain handheld equipment for applications to turf or gardens (e.g., bellygrinder). This general trend was essentially the same for exposures of any duration. Several data gaps were also identified in many different use areas that include: dust use for animal grooming and in agriculture; various specialized hand equipment application methods (e.g., powered backpack, power hand fogger, and tree injection); and nursery operations such as seedling dips.

The risk of cancer for occupational handlers was calculated for two populations, private growers (10 applications per year) and commercial applicators (30 applications per year), using the same 28 scenarios. According to Agency policy, acceptable cancer risks for occupational exposure to pesticides can vary from $1x10^{-4}$ to $1x10^{-6}$, depending on the course of action taken by the Agency as outlined in the

the subject policy[2]. Risks for corresponding scenarios based on cancer concerns were generally less than the corresponding noncancer results across all scenarios. In fact, in all but one scenario, cancer risks were $<1x10^{-4}$ at current carbaryl label requirements of single layer clothing, gloves, and no respirator for both private growers and commercial applicators (i.e., mixing/loading wettable powders for wide area aerial applications). Higher levels of personal protection reduce this risk to $<1x10^{-4}$ in both populations. If a $1x10^{-6}$ risk level is specified as a concern, results are similar in that risks for a majority of scenarios are $<1x10^{-6}$ at current label requirements. In fact, only 8 of the 128 scenarios considered for private applicators have cancer risks $>1x10^{-6}$ (and less than $1x10^{-4}$) even with the most protective ensembles of protective clothing or engineering controls. For commercial applicators, results indicate that risks for about half of the scenarios considered are $<1x10^{-6}$ at current label requirements and that only 21 of the 128 scenarios considered have cancer risks $>1x10^{-6}$ (and less than $1x10^{-4}$) even with the most protective ensembles of either protective clothing or engineering controls.

Occupational Postapplication (Reentry Workers):

Workers can be exposed to carbaryl residues when entering previously treated areas to perform certain activities, such as harvesting. Current label requirements specify 12 hour Restricted Entry Intervals (REIs) while Pre-Harvest Intervals (PHIs) are less than 7 days for most crops with some as long as 28 days. Non-cancer risks from short- and intermediate-term dermal postapplication exposure were calculated for 18 representative crop groupings using the MOE approach. The risks from long-term dermal exposures were calculated for only a limited number of scenarios in the greenhouse and floriculture industries. For each scenario, the risk on the day of application was calculated, along with the time required to reach the target MOE, allowing for dissipation of the carbaryl residues. For all but the lowest exposure scenarios in some crops, MOEs do not meet or exceed target MOEs until several days after application. If short-term risks are considered, MOEs meet or exceed target MOEs generally in the range of 3 to 5 days after application for lower to medium exposure activities and from 8 to 12 days after application in most higher exposure scenarios. If intermediate-term risks are considered, MOEs are not of concern based on a 30 day average exposures except for higher level exposures such as harvesting in some crops. Chronic exposures are of concern for the cut flower industry but not for other general greenhouse and nursery production activities based on the most recent data.

Cancer risks were calculated for private growers and professional farmworkers with the only difference being the annual frequency of exposure days. Cancer risks for private growers and commercial farmworkers are generally in the 10^{-8} to 10^{-6} range on the day of application. If a $1x10^{-4}$ cancer risk is the target, the current REI would be adequate for all scenarios considered in the

[2] The Agency has defined a range of acceptable cancer risks based on a policy memorandum dated August 14, 1996, by Office of Pesticide Programs Director Dan Barolo. This memo refers to a predetermined quantified "level of concern" for occupational carcinogenic risk. Occupational carcinogenic risks that are 1×10^{-6} or lower require no risk management action. For those chemicals subject to reregistration, the Agency is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protection are warranted as is commonly applied with noncancer risk estimates (e.g., additional PPE or engineering controls). Carcinogenic risks that remain above 1.0×10^{-4} at the highest level of mitigation appropriate for that scenario remain a concern.

assessment. If a $1x10^{-6}$ cancer risk is used, then durations longer than the current REI should be considered for some cases which are not considered low to medium exposures. It should be noted that the cancer risk calculations are less restrictive than noncancer risk estimates for the same scenarios in all cases. Many mechanized or partially mechanized processes are possibly associated with the use of carbaryl that may limit or eliminate exposures (e.g., combines for grain harvest).

Human and Domestic Animal Incidents:

HED evaluated reports of human carbaryl poisonings and adverse reactions associated with its use from the following sources: OPP Incident Data System (IDS); Poison Control Centers' Toxic Exposure Surveillance System; California Department of Pesticide Regulation; the National Pesticide Telecommunications Network (NPTN); open literature; and an unpublished study submitted by the registrant. The data from IDS indicated that a majority of cases from carbaryl exposure involved dermal reactions. A number of other cases involved asthmatics and people who experienced hives and other allergic type reactions. It is noted that the dermal sensitization study in the guinea pig was negative. Reports of allergic-type reactions in humans could be evidence of a difference in species sensitivity or could be attributable to inert ingredients in the marketed formulations. It is recommended that labels for products should advise that carbaryl can cause sensitizing effects in some people. According to California data, about half of the cases involved skin and eye effects in handlers. About a quarter of the skin reactions were due to workers that were exposed to residues on crops. Reports from the literature are very limited but tend to support the finding that carbaryl has irritant properties. The Poison Control Center cases involving non-occupational adults and older children showed an increased risk in five of the six measures used for comparing carbaryl incidents to all other pesticides. The carbaryl cases were almost twice as likely to require serious health care (hospitalization or treatment in a critical care unit) and were two and a half times more likely to experience major medical outcome (life-threatening effects or significant residual disability) than other pesticides. This pattern of increased risk was not seen among occupational reports or in young children. This may mean that careless handling by non-professionals is a particular hazard. Five case report studies suggested that carbaryl may be a cause of chronic neurological or psychological problems. Some of these effects appear to be consistent with those reported from organophosphate poisoning. However, unlike organophosphates, no controlled studies have been undertaken. If such effects occur as a result of over-exposure to carbaryl, they appear to be relatively rare. The effects reported among the five case reports are too inconsistent to draw any conclusions, but do suggest the need for further study. The epidemiologic study submitted by the registrant compared mortality rates in plant workers exposed to carbaryl to the general population. HED concluded that the sample of workers was too small and the period of follow-up too short to permit definitive conclusions.

The incident reports on domestic animals in IDS were evaluated. Based on limited data, there is some evidence that young kittens may be susceptible to adverse reactions to carbaryl. It is recommended that all labels for carbaryl products used on cats contain the age restriction stated in PR Notice 96-6 (should not be used in kittens less than 12 weeks of age).

Issues For Consideration:

There are population-based monitoring studies in the published literature or available from various governmental agencies in which carbaryl metabolites are measured in body fluids or environmental media. For example, the Agency's Office of Research and Development, along with other Agencies, has funded a project entitled *Pesticide Exposure in Children Living in Agricultural Areas along the United States-Mexico Border Yuma County, Arizona*. Preliminary results of this study indicate that carbaryl residues were identified in the dust of 20 percent of the 152 houses sampled and in approximately 24 percent in 25 samples collected in 6 schools in the same region. With regard to this specific example, current Agency policy is not to use house dust estimates to calculate risks because of a lack of an appropriate exposure model. Also, in a 1995 study conducted by the Centers For Disease Control (Hill et al) entitled *Pesticide Residues In Urine Of Adults Living In The United States: Reference Range Concentrations*, 1000 adults were monitored via urine collection. One of the analytes measured in that study (1-naphthol) is a potential metabolite of carbaryl as well as of napthalene and napropamide which may be a confounding factor. This metabolite (1-naphthol) was identified in 86 percent of the 1000 adults monitored. Data from this study were not used quantitatively in the risk assessment for carbaryl because of the uncertainties associated with them, such as the exact contribution of each possible compound to the overall levels and no linked exposure information. HED instead considered them a qualitative indicator that exposures in the general population are likely to occur. As more data become available, the Agency will consider the information in an effort to refine the assessment. It should also be noted that Aventis Crop Science has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental flowers. A biomonitoring study of field workers during harvesting and hand thinning operations in apples and cherries will also be submitted to the Agency. Based on personal communication with Aventis Crop Science scientists, preliminary results from the residential biomonitoring study indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are intended to represent the higher percentiles of the exposure distribution. Preliminary field worker results also appear to not be significantly different from Agency estimates.

The database for carbaryl contains good quality studies which are sufficient for conducting a risk assessment for the reregistration of the chemical. However, certain key information, which would help refine the risk assessment, is missing. The one toxicology data gap includes a 90-day inhalation study in the rat. The elimination of poultry from the acute and chronic dietary risk assessment significantly reduced the risks. For residential postapplication risk assessments, there are no data on the amount of residues transferrable from treated pets to humans. Additional residue data on turf would also help refine the hand-to-mouth and object-to-mouth toddler exposures. For the occupational handler risk assessments, several handler scenarios lack high quality data. For postapplication workers, additional residue dissipation data along with data from practices not well represented in Agency Policy 003 (Transfer Coefficients) are needed to refine the assessment (e.g., partially mechanized practices that could involve contact).

2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION

The product chemistry chapter was prepared by Felicia Fort of the Health Effects Division (November 14, 2000 - DP Barcode 240989). All information below is excerpted from that chapter unless specifically noted. *Section 2.1: Chemical Structure and Identification* presents the nomenclature and structures associated with carbaryl and its metabolites. *Section 2.2: Physical Properties of Carbaryl* presents information about the properties of carbaryl.

2.1 Chemical Structure and Identification

Chemical Name: 1-naphthyl methylcarbamate
Empirical Formula: $C_{12}H_{11}NO_2$
Molecular Weight: 201.2
CAS Registry No.: 63-25-2
Chemical ID No.: 056801
Structures of carbaryl and major metabolites are shown below in Figure 1.

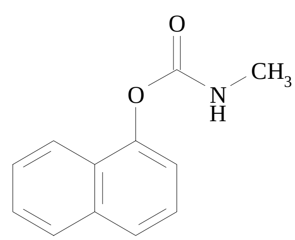
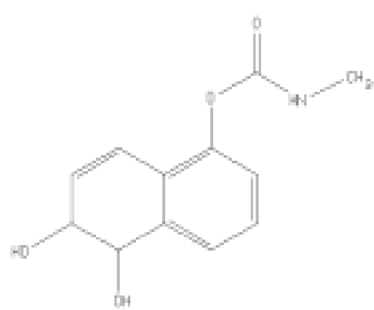
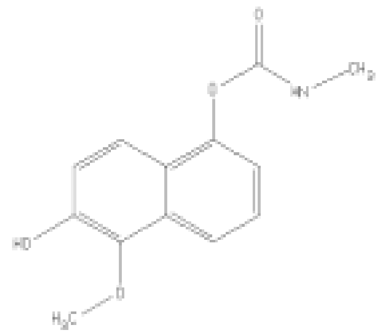
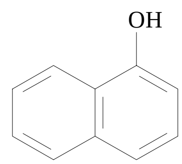
Figure 1. Structures of Carbaryl and Major Metabolites	
Name	Structure
Carbaryl 1-Naphthyl N-methylcarbamate	
5,6-dihydro-5,6-dihydroxy carbaryl	

Figure 1. Structures of Carbaryl and Major Metabolites

Name	Structure
5-methoxy-6-hydroxy carbaryl	
1-Naphthol	

2.2 Physical Properties of Carbaryl

Physical state: white to light tan solid
Melting point: 142^{0}C
Solubility: water (40 ppm at 25 C), dimethyl formamide ($\leq$45 g/100 mL); acetone, cyclohexanone, and isophorone ($\leq$25 g/100 mL); methylethyl ketone ($\leq$20 g/100 mL); dichloromethane ($\leq$15 g/100 mL); ethanol and ethyl acetate ($\leq$10 g/100 mL); mixed aromatic solvents and xylene ($\leq$3 g/100 mL); and kerosene ($\leq$1 g/100 mL).
Vapor pressure: 0.000041 mm Hg at 26^{0}C[3]
Specific gravity: 1.23 at 20^{0}C
Octanol/water partition coefficient (K_{ow}): 217

[3] From the EPA Technology Transfer Network, Office of Air Quality Planning and Standards, Air Toxics Website (www.epa.gov/ttn/atw)

3.0 HAZARD CHARACTERIZATION

The hazard component of the risk assessment is presented in this section. *Section 3.1: Hazard Profile* presents a discussion of the available toxicity data for carbaryl. *Section 3.2: FQPA Considerations* discusses the susceptibility of sensitive populations such as children and the uncertainties associated with that analysis. *Section 3.3: Dose Response Assessment* describes which data were selected for risk assessment purposes. *Section 3.4: Endocrine Disruption* describes issues related to EDSTAC and the screening process for possible chemicals of concern.

3.1 Hazard Profile

The updated Toxicology Chapter of the RED was prepared by Dr. Virginia Dobozy (D282980). The toxicology data base is of good quality and is essentially complete. A 90-day inhalation study with cholinesterase measurements is required. The database provides sufficient information for selecting toxicity endpoints for risk assessment and therefore, supports a reregistration eligibility decision for the currently registered uses.

Carbaryl is a carbamate insecticide. Its primary mode of toxic action is through cholinesterase inhibition (ChEI) after single or multiple exposures. In most of the toxicology studies in which ChEI was measured, it was the endpoint used to set the Lowest Observed Adverse Effect Level (LOAEL).

The acute toxicity studies showed that carbaryl was relatively toxic with acute oral dosing (Tox. Category II); but the acute dermal and inhalation toxicities were low (Tox. Categories III and IV, respectively). Carbaryl was not a dermal or eye irritant and was not a dermal sensitizer in animal studies (Table 1). However, human incidents of dermal irritation and dermal manifestations of an allergic response have been reported (see section 7.4 below for more information).

Table 1: Acute Toxicity of Carbaryl

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-1	Acute Oral - rat (99% a.i.)	00148500	LD_{50} for males = 302.6 mg/kg; for females = 311.5 mg/kg; combined = 307.0 mg/kg	II
81-2	Acute Dermal -rabbit (99% a.i.)	00148501	LD_{50} > 2000 mg/kg	III
81-3	Acute Inhalation - rat (99% a.i.)	00148502	LC_{50} > 3.4 mg/L	IV
81-4	Primary Eye Irritation - rabbit (99% a.i.)	00148503	not a primary eye irritant	IV
81-5	Primary Skin Irritation - rabbit (99% a.i.)	00148504	not a primary skin irritant	IV

Table 1: Acute Toxicity of Carbaryl				
Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-6	Dermal Sensitization - guinea pig (99% a.i.)	00148505	negative	NA
81-7	Acute Delayed Neurotoxicity (Hen)	*	negative at 2000 mg/kg (approximate LD_{50})	NA
81-8	Acute Neurotoxicity - rat	43845201-43845204	systemic LOAEL = 10 mg/kg for males and females based on significant inhibition of RBC, plasma, whole blood and brain cholinesterase; NOAEL < 10 mg/kg	

a.i. = active ingredient
* Carpenter, C.P., Weil, C.S., Palm, P.E., Woodside, N.W., Nair, J. H. and Smyth, H.F. Mammalian Toxicity of 1-napthyl-N-methyl carbamate (Sevin Insecticide). J. Agric. Food Chem. 9(1): 30-39, 1961.

The neurotoxicity data showed that carbaryl was not a delayed neurotoxicant in the hen. In the acute neurotoxicity study in the rat after a single dose of 10 mg/kg carbaryl, ChEI was observed in plasma, whole blood, red blood cells (RBC) and brain. At the next higher dose (50 mg/kg), clinical signs typical of carbamate toxicity were observed. In the subchronic neurotoxicity study after 90 days of administration, clinical signs of toxicity were seen at the same dose (10 mg/kg/day) as plasma, whole blood, RBC and brain ChEI. There was no evidence of structural neuropathology in these studies.

No subchronic studies in the rat or dog are available, except for the subchronic neurotoxicity study in rats and 4-week dermal toxicity studies in rats (one with technical chemical and two with formulations). One of the dermal toxicity studies was useful for risk assessment. In this study, the systemic NOAEL was 20 mg/kg/day based on decreased RBC ChEI in males and females and brain ChEI in males at 50 mg/kg/day. The chronic toxicity data showed that, in dogs, decreases in plasma, RBC and brain ChEI were observed at 10 mg/kg/day; clinical signs of toxicity were also observed in both sexes at 31 mg/kg/day. Brain and plasma ChEI were decreased in female dogs at 3.1 mg/kg/day. In the mouse, clinical signs of toxicity were not typical of ChEI, but there was ChEI (plasma, RBC and brain) at 146 mg/kg/day. In the chronic toxicity study in rats, carbaryl at the highest dose (350 mg/kg/day in males and 485 mg/kg/day in females) caused a variety of toxic effects in the liver, kidneys and urinary bladder. It also induced an increase in the incidence of thyroid follicular cell hypertrophy and degeneration of sciatic nerves and skeletal muscle. RBC ChEI was decreased in males at 60 mg/kg/day and in females at 79 mg/kg/day. The lowest LOAEL in the chronic studies was in the chronic dog study, i.e., 3.1 mg/kg/day, which was the lowest dose in females. In a follow-up 5-week study in dogs to clarify the NOAEL for ChEI, plasma ChEI was decreased in males at 3.83 mg/kg/day; no effects were observed at 1.43 mg/kg/day.

In a prenatal developmental toxicity study in the rat, maternal toxicity was observed at the same dose (10 mg/kg/day) as developmental toxicity; the NOAEL was 4 mg/kg/day. Developmental effects included decreased fetal body weight and increased incomplete ossification of multiple bones. In a prenatal developmental toxicity study in the rabbit, the maternal and developmental LOAELs were 50 mg/kg/day and 150 mg/kg/day, respectively. The respective NOAELs were 5 mg/kg/day and 50 mg/kg/day. The only evidence of developmental toxicity was a decrease in fetal body weight. These studies showed no evidence of a qualitative or quantitative increased susceptibility. In the reproduction study, there was evidence of a quantitative offspring susceptibility. The LOAEL for parental systemic toxicity was 1500 ppm (92.43-124.33 mg/kg/day for males and 110.78-135.54 mg/kg/day for females) based on decreased body weight, weight gain, and feed consumption. The NOAEL was 300 ppm (23.49-31.34 mg/kg/day for males and 26.91-36.32 mg/kg/day for females). The LOAEL for offspring toxicity was 300 ppm (23.49-31.34 mg/kg/day for males and 26.91-36.32 mg/kg/day for females) based on increased numbers of F_2 pups with no milk in the stomach and decreased pup survival. The NOAEL was 75 ppm (4.67-5.79 mg/kg/day for males and 5.56-6.41 mg/kg/day for females). In the developmental neurotoxicity study, there was evidence of qualitative susceptibility. Clinical signs of toxicity and plasma and brain ChEI were seen in maternal animals at the same dose (10 mg/kg/day) as changes in brain morphometric measurements (decreases in cerebellar measurements in females on Day 11 post-partum) were observed in offspring; however, brain measurements were not conducted at the next lower dose.

The Health Effects Division's (HED) Cancer Assessment Review Committee (CARC)(11/7/01) classified carbaryl as *Likely* to be carcinogenic in humans based on an increased incidence of hemangiosarcomas in male mice at all doses tested (100, 1000 and 8000 ppm). The Q_1*, based on the CD-1 mouse dietary study with ¾ Interspecies Scaling Factor, is 8.75×10^{-4} $(mg/kg/day)^{-1}$ in human equivalents. In addition to the required carcinogenicity studies in mice and rats, the registrant submitted a special study in genetically modified mice. Carbaryl was administered to heterozygous p53-deficient (knockout) male mice in the diet at concentrations of up to 4000 ppm (716.6 mg/kg/day) for six months. There was no evidence of neoplastic or preneoplastic changes in the vascular tissues of any organ. A model validation study demonstrated that vascular tumors occur in heterozygous p53 deficient mice within six months of administration of a known genotoxic carcinogen (urethane).

A recent review of the data from the submitted studies and the published literature show that carbaryl is clastogenic *in vitro.* The wide variety of induced aberrations (both simple and complex) was consistent between the submitted micronucleus study and the open literature. However, there are inconsistencies relative to the requirement for S9 activation. Nevertheless, the two *in vivo* studies for micronuclei induction or chromosome aberrations were negative. Similarly, the 6-month p53 knockout transgenic mouse bioassay was negative. Carbaryl was also negative for DNA binding in the livers of mice treated with 8000 ppm for 2 weeks. Metabolism studies identified epoxide intermediates of carbaryl which were found to be conjugated to glucuronide, rapidly metabolized and excreted as any endogenous epoxide would be. Overall, these findings indicate that carbaryl produces epoxides and its DNA reactivity is manifested as chromosomal aberrations in cultured mammalian cells. Other *in vitro* studies indicate carbaryl's effects on karyokinesis and cytokinesis, as well as stress genes associated with oxidative damage. Based on these considerations, the CARC concluded that there is a concern for mutagenicity, which is somewhat lessened because of the lack of an effect in *in vivo* mutagenicity studies.

The metabolism data in the rat indicated that radiolabeled carbaryl was readily absorbed with oral dosing, distributed to various organs, metabolized and formed conjugated metabolites with compounds such glucuronic acid. A total of 20 components was found, and 2 major metabolites were identified, naphthyl sulfate and naphthyl glucuronide. Much of the radioactivity was eliminated within 24 hours after dosing (86% in urine and 11% in feces). Seven days post dosing, negligible amounts of the administered dose were found in tissues. Several special metabolism studies were conducted to explore a mechanism for the increase in tumor incidence in mice. The results appear to show that high doses of carbaryl treatment (1154 mg/kg) led to a "phenobarbital" type of induction of liver xenobiotic-metabolizing enzymes and interaction of carbaryl with chromatin protein in mice. A dermal absorption study indicated that 12.7% of a carbaryl formulation (43.9% a.i.) was absorbed.

The toxicology profile for carbaryl is presented in Appendix 1.

3.2 FQPA Considerations

The HIARC (February 19, 2002 meeting) concluded that there is a concern for pre- and/or postnatal toxicity resulting from exposure to carbaryl.

3.2.1 Determination of Susceptibility

There was no evidence of quantitative or qualitative susceptibility following *in utero* exposures in developmental studies in the rat and rabbit.

In the reproduction study, there was evidence of quantitative susceptibility of offsprings. The LOAEL for parental systemic toxicity was based on decreased body weight, weight gain, and feed consumption; the NOAEL was 27 mg/kg/day in males and 30 mg/kg/day in females. In the offspring the LOAEL was based on increased numbers of F_2 pups with no milk in the stomach and decreased pup survival; the NOAEL was 5 mg/kg/day in males and 6 mg/kg/day in females. No adverse effects were observed in the reproductive parameters.

In the developmental neurotoxicity study, there was evidence of qualitative susceptibility. For maternal toxicity, the LOAEL was based on decreased body weight gain, alterations in Functional Observational Battery measurements and inhibition of plasma, whole blood and brain cholinesterase activity; the NOAEL was 1 mg/kg/day. For developmental neurotoxicity, the LOAEL was based on the morphometric changes seen in the brain of the offsprings; the NOAEL was 1 mg/kg/day.

3.2.2 Degree of Concern Analysis and Residual Uncertainties

The HIARC concluded that there is no residual concern in the two-generation reproduction study because the dose-response effects in pups are well-characterized and the NOAEL for the offspring effects is above that which was used for establishing the chronic Reference Dose (RfD) for chronic dietary risk assessment.

The HIARC selected the LOAEL of 3.1 mg/kg/day established in the chronic toxicity study in dogs for establishing the chronic RfD. Since a LOAEL was used, an additional uncertainty factor of 3X was applied (i.e, lack of a NOAEL) to the LOAEL. Although a NOAEL was not established in this study, the HIARC determined that a 3X was adequate (as opposed to a higher value) because: 1) cholinesterase inhibition in females was not accompanied by clinical signs; 2) no inhibition was seen for any cholinesterase compartment in males at this dose; 3) the magnitude of inhibition of plasma cholinesterase inhibition (12-23% decrease) was comparable to the magnitude of inhibition (22%) seen in the 5-week study in dogs indicating no cumulative effects following long-term exposure; 4) the study was well-conducted and there are sufficient data from subchronic and chronic duration studies in the other species which support cholinesterase inhibition as the critical effect.

In addition, based on the cholinesterase inhibition data, the dog appears to be more sensitive than the rat in long-term studies. Furthermore, use of the LOAEL of 3 mg/kg/day from the 1-year dog study with an uncertainty factor of 300 results in a NOAEL of 1 mg/kg/day. This extrapolated NOAEL is identical to that of the offspring NOAEL of 1.0 mg/kg/day established in the developmental neurotoxicity study.

Thus, the NOAEL of 1 mg/kg/day used for establishing the chronic RfD is below the NOAEL of 5 mg/kg/day for offspring toxicity, and the chronic RfD would be protective of the effects of concern for infants and children following chronic dietary exposures.

With regard to the developmental neurotoxicity study, the HIARC concluded that there was a low level of concern based on the following residual uncertainties:

- The first uncertainty was the lack of a demonstrated effect level since morphometric measurements of brains in the offsprings were not performed at the mid-dose (1 mg/kg/day). However, this concern was negated since even at the high dose of 10 mg/kg/day, the morphometric changes were minimal and therefore, it is unlikely that adverse effects would be seen at 1 mg/kg/day, which is 10% of the LOAEL.

- The second uncertainty was the lack of comparative data in adults and offspring for cholinesterase inhibition. This concern was negated since no FOB alterations were seen in pups. Other studies in the data base have shown that when FOB alterations were seen in adult animals, they are usually accompanied with cholinesterase inhibition. Also, the results of the National Institute for Environmental Health Sciences study (discussed above) showed no difference in cholinesterase inhibition in pups and adults. There was a dose-related decrease in cholinesterase activity in the brain and blood of dams at gestation day 19 and fetuses taken at this time also showed a very similar level of fetal brain cholinesterase.

The HIARC concluded that the NOAEL of 1 mg/kg/day selected for establishing the acute RfD would address the low level of concern for the residual concerns and would be protective of the effects of concern for infants and children following a single oral exposure.

3.3 Dose Response Assessment

The HIARC evaluated the toxicology data base of carbaryl, reassessed the Reference Dose (RfD) established in 1994 and selected the toxicological endpoints for acute dietary, as well as occupational and residential exposure risk assessments at a meeting on July 7, 1998. Re-evaluations of the FQPA Safety Factor recommendation were done on April 28 and November 15, 1999, after the submission of prenatal developmental toxicity studies in the rat and rabbit, respectively. A re-evaluation of the endpoints for risk assessment was conducted on March 1, 2001, February 19, 2002 and April 25, 2002. Table 2 contains a summary of the hazard doses and endpoints selected for use in the various human health risk assessments. Endpoints were selected for a broad spectrum of risk assessments, including acute and chronic dietary, short-, intermediate- and long-term dermal and inhalation exposures and short- and intermediate-term incidental exposure. For the chronic dietary and the long-term dermal and inhalation exposure endpoints, a LOAEL was selected, which necessitated an additional 3x uncertainty factor.

A common toxicological endpoint exists for the dermal, inhalation and incidental oral routes. Therefore, the Margins of Exposure (MOEs) can be combined for occupational and residential risk assessments. For acute, short- , intermediate- and long-term aggregate risk assessments, the oral, dermal and inhalation routes can be combined because of the common toxicity endpoint (ChEI).

Table 2. Summary of Toxicological Dose and Endpoints for Carbaryl for Use in Human Risk Assessment

Exposure Scenario	Dose (mg/kg/day) & Total UF	Hazard Based Special FQPA Safety Factor	Endpoint for Risk Assessment
Dietary & Nondietary Ingestion Risk Assessments			
Acute Dietary general population including infants and children	NOAEL = 1 UF = 100	1	**Developmental Neurotoxicity - rat** LOAEL = 10 mg/kg/day based on an increased incidence of FOB changes on the first day of dosing in maternal animals **Acute RfD and aPAD** = 0.01 mg/kg/day

Table 2. Summary of Toxicological Dose and Endpoints for Carbaryl for Use in Human Risk Assessment			
Exposure Scenario	**Dose (mg/kg/day) & Total UF**	**Hazard Based Special FQPA Safety Factor**	**Endpoint for Risk Assessment**
Chronic Dietary all populations	LOAEL= 3.1 UF = 300	1	**Chronic toxicity - dog** LOAEL = 3.1 mg/kg/day based on plasma and brain cholinesterase inhibition in females. **Chronic RfD and cPAD** = 0.01 mg/kg/day [Note: A NOAEL could not be defined in this study. Therefore, an additional factor of 3 has been applied to account for the data deficiency.]
Short-term Incidental Oral (1 - 30 Days) [Residential Only]	NOAEL= 1 Res. UF = 100	1	**Developmental Neurotoxicity - rat** LOAEL = 10 mg/kg/day based on an increased incidence of FOB changes and decreases in RBC, whole blood, plasma and brain cholinesterase
Intermediate-Term Incidental Oral (1 - several months) [Residential Only]	NOAEL= 1 Res. UF = 100	1	**Subchronic Neurotoxicity - rat** LOAEL = 10 mg/kg/day based on increased incidence of FOB changes; decrease in RBC, whole blood, plasma and brain cholinesterase.
Non-Dietary Risk Assessments			
Short-Term Dermal (1 - 30 days)	NOAEL= 20 Res. UF = 100 Occ. UF = 100	1	**4-week dermal toxicity with technical - rat** systemic LOAEL = 50 mg/kg/day based on statistically significant decreases in RBC cholinesterase in males and females and brain cholinesterase in males.
Intermediate-term Dermal (30 days - several months)	NOAEL= 20 Res. UF = 100 Occ. UF = 100	1	**4-week dermal toxicity with technical - rat** systemic LOAEL = 50 mg/kg/day based on statistically significant decreases in RBC cholinesterase in males and females and brain cholinesterase in males.
Long-Term Dermal (Several months to a lifetime)	LOAEL= 3.1 Res. UF = 300 Occ. UF = 300	1	**Chronic toxicity - dog** LOAEL = 3.1 mg/kg/day based on plasma and brain cholinesterase inhibition in females. [Note: A NOAEL could not be defined in this study. Therefore, an additional factor of 3 has been applied to account for the data deficiency. Also, this study is not route-specific as it was conducted via oral administration. Route-to-route extrapolation is required using an adsorption factor of 12.7 percent which is based on a rat dermal absorption study.]
Short-Term Inhalation (1 - 30 days)	NOAEL= 1 Res. UF = 100 Occ. UF = 100	1	**Developmental Neurotoxicity - rat** LOAEL = 10 mg/kg/day based on an increased incidence of FOB changes and statistically significant decreases in RBC, whole blood, plasma and brain cholinesterase [Note: This study is not route-specific as it was conducted via oral administration. Route-to-route extrapolation is required using an adsorption factor of 100 percent.]

Table 2. Summary of Toxicological Dose and Endpoints for Carbaryl for Use in Human Risk Assessment			
Exposure Scenario	**Dose (mg/kg/day) & Total UF**	**Hazard Based Special FQPA Safety Factor**	**Endpoint for Risk Assessment**
Intermediate-Term Inhalation (30 days - several months)	NOAEL= 1 Res. UF = 100 Occ. UF = 100	1	**Subchronic Neurotoxicity - rat** LOAEL = 10 mg/kg/day based on increased incidence of FOB changes; decrease in RBC, whole blood, plasma and brain cholinesterase. [Note: This study is not route-specific as it was conducted via oral administration. Route-to-route extrapolation is required using an adsorption factor of 100 percent.]
Long-Term Inhalation (Several months to a lifetime) [Occupational only]	LOAEL= 3.1 Occ. UF = 300	1	**Chronic toxicity - dog** LOAEL = 3.1 mg/kg/day based on plasma and brain cholinesterase inhibition in females. [Note: A NOAEL could not be defined in this study. Therefore, an additional factor of 3 has been applied to account for the data deficiency. Also, this study is not route-specific as it was conducted via oral administration. Route-to-route extrapolation is required using an adsorption factor of 100 percent.]
Cancer	**Classification: C** $\mathbf{Q_1^*}$ = 8.75×10^{-4} (mg/kg/day)$^{-1}$		

3.4 Endocrine Disruption

EPA is required under the Federal Food Drug and Cosmetic Act, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, carbaryl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

4.0 NON-OCCUPATIONAL RISK ASSESSMENT AND CHARACTERIZATION

This section of the risk assessment addresses exposures to individuals in the general population that are not exposed as part of their employment. These exposures can occur through the diet and/or they can occur because people have contact with carbaryl residues while using consumer products containing carbaryl or by being in areas that have been previously treated. *Section 4.1: Summary of Registered Uses* below summarizes available products and also describes the uses of those products. Products intended for commercial sales (e.g., in agriculture) and consumer products are included as each type of product can contribute to non-occupational exposures through the diet, via residential use, or through commercial use in areas frequented by the general population such as golf courses. *Section 4.2: Dietary Risk Assessment* describes the residue and consumption data used in the dietary risk assessment, the risks associated with various populations of interest through the diet, and characterization of those risks. *Section 4.3: Water Risk Assessment* describes how water concentrations were determined, calculation of risks, and characterization of those risks. *Section 4.4: Residential Risk Assessment* describes how risks were calculated for people who use consumer products containing carbaryl and for those who are exposed as a result of being in areas that have been previously treated.

4.1 Summary of Registered Uses

All products (e.g., manufacturing and various end-use formulations) and the associated use patterns for carbaryl are described below. A brief overview of the types of equipment and application rates is also provided. The information in this section summarizes all use patterns of carbaryl as both commercial products and products intended for sale to homeowners can both contribute to exposures in the general population through the diet, drinking water, direct use (i.e., for homeowners only in this aspect of the risk assessment) and as a result of people frequenting areas that have been previously treated by either homeowners (e.g., lawns or gardens) or other public places that could have been commercially treated (e.g., golf courses). The need to have a thorough understanding of the use patterns for consumer products is self explanatory. Understanding the use of commercial products is key for the development of the dietary and drinking water assessments. It is also critical for evaluating some residential postapplication exposures such as for golfers.

Carbaryl (1-naphthyl N-methyl-carbamate) is a broad-spectrum carbamate insecticide marketed in a variety of end-use products for both occupational and homeowner use. End-use product names include Adios, Bugmaster, Carbamec, Carbamine, Crunch, Denapon, Dicarbam, Hexavin, Karbaspray, Nac, Rayvon, Septene, Sevin, Tercyl, Tornado, Thinsec, and Tricarnam. Use sites include but are not limited to the following: fruit and nut trees; vegetable crops; field and forage crops; grapes; forestry; lawns and other turf such as golf courses; ornamental trees, shrubbery, annuals, and perennials; wide area treatment targets such as residential mosquito adulticide uses and oyster beds; poultry production facilities; and companion animals (e.g., dogs and cats). Table 3 summarizes all (homeowner and occupational products) currently available technical and manufacturing products along with their corresponding EPA registration numbers.

Table 3: Technical and Manufacturing Carbaryl Products	
Formulation	EPA Reg. No. (% active ingredient)
Technical	34704-707 (99%); 45735-24 (99%); 264-324 (99%),-325 (97.5%); 19713-75 (99%)
Manufacturing Product	264-328 (80%); 264-325 (97.5%) 769-971 (80%); 5481-190 (46%) 19713-369 (50 %); 432-982 (97.5%); 73049-238 (1%)

Based on a review (2/27/01) of the *Office of Pesticide Programs – Reference Files System (REFS)*, there are over 300 active product labels (i.e., includes both homeowner and occupational products). Carbaryl formulations include dusts, emulsifiable concentrates, soluble concentrates, water dispersible granulars, flowable concentrates, wettable powders, granulars, baits, pet dips and pet shampoos, aerosol sprays, ready-to-use pump sprayers, and pet collars (i.e., treated articles). Table 4 summarizes the approximate number of Section 3-registered products in each formulation category and the range of percent active ingredient. A complete listing of all the registration numbers under each category can be found in the Occupational/Residential Exposure Assessment chapter (D281418). This chapter also includes in the Appendices, the *Qualitative Usage Analysis For Carbaryl* and the *RED Use Profile Report* prepared by the Agency's Biological and Economic Analysis Division. Many of the products described can be used in a variety of settings ranging from agriculture and commercial facilities to residential areas.

Table 4: Carbaryl End-Use Product Formulations		
Formulation Type	Number of Products	Range of Percent Active Ingredient
Emulsifiable Concentrates & Flowable Concentrates	57	0.3 - 80
Wettable Powders & Soluble Granules	36	0.5 - 95
Dusts	130	0.3 - 80
Granular	45	1.43 - 15
Bait	55	1.3 - 13
Dips, Shampoos	2	0.5 - 60
Pet collars (treated articles)	2	8.5 - 16
Ready to Use Pump Sprayers & Aerosol Cans	6	0.12 - 1

Equipment used to apply carbaryl in residential settings includes dust shaker cans, garden hose-end sprayers, trigger sprayers, low pressure handwands, belly grinders, push-type spreaders, aerosol cans, and pet collars. In an occupational setting, carbaryl can be applied by airblast, aerial application, chemigation, groundboom, power duster, low and high pressure handwand, backpack, compressed air sprayer, fogger, hand-held duster, hose-end sprayer, duster cans, and aerosol can. Depending on the crop, the maximum number of carbaryl applications per season can range from 1 to 8. A variety of application rates are available on the carbaryl labels, ranging from 1 lb ai/acre for curcurbits to 16 lb ai/acre for a foliar treatment of citrus in California. Some products are marketed in a single marketplace while others are sold for use in various settings. Based on sales information provided by Aventis CropScience at the SMART meeting with EPA on September 24, 1998, it appears that approximately 34 percent of carbaryl use is by homeowners in residential settings, 59 percent is used in agriculture, and the remaining 7 percent is used in the nursery, landscape and golf course industries.

The application parameters for major crop groups or application targets were defined by the physical nature of the use site, the physical nature of the formulation, the equipment needed for application and the application rate. Selected crop groupings and application targets along with corresponding typical (if available) and maximum application rates that are used in the risk assessment are presented in Table 5 below.

Table5: Application Rates Considered in Risk Assessment

Crop or Target	Occupational Products				Residential Products lb ai/1000 ft^2 (units may vary)
	lb ai/A/acre (units may vary)	max. apps/season	lb ai/season	Average Rates	
Alfalfa, clover, trefoil	1.5	1/cutting	1.5/cutting	1.1	-
Asparagus	2 4 - postharvest	3 - broadcast 2 - postharvest	6 - broadcast 10 - postharvest	0.9	0.023 -0.094
Beans (fresh & dried), cowpeas, peas	1.5	4	6	0.9	0.012-0.047
Beets, carrot, horseradish, radish, parsnip	2 - foliar 2.2 - soil broadcast	6 - foliar 4 - soil	6	0.8	0.012-0.047
Blueberries	2 - foliar 0.5 lb/1000 ft^2 - soil	5	10	1.7	0.012-0.047
Cole Crops (broccoli, brussel sprouts, cabbage, cauliflower, chinese cabbage, collards, kale, kohlrabi, mustard greens)	2 - foliar 2.2 - soil broadcast	4	6	0.8	0.012-0.047
Caneberries	2 - foliar 2.2 - soil broadcast	5 4	10 Not specified	1.7	0.012-0.047
Celery, Dandelion	2 - foliar 2.2 - soil broadcast	4	6	1.0	0.012-0.047
Citrus	16 (foliar in CA only) 10 (foliar in FL only) 7.5 - foliar 1 lb/100 gal.	1 Not specified 8 Not specified	20 Not specified 20 Not specified	2.7 to 3.4 (lemons & oranges)	0.023-0.176
Corn (field and pop)	2	4	8	1.0	0.012-0.047

Table5: Application Rates Considered in Risk Assessment					
Crop or Target	Occupational Products				Residential Products lb ai/1000 ft^2 (units may vary)
	lb ai/A/acre (units may vary)	max. apps/season	lb ai/season	Average Rates	
Corn (sweet)	2 - foliar 2.2 - soil broadcast	8 4	16 Not specified	1.3	0.012-0.047
Cranberry	2	5	10	2.0	0.012-0.047
Cucurbits (cucumber, melon, pumpkin, squash)	1	6	6	1.1	0.012-0.047
Fruiting Vegetable (tomato, eggplant, pepper)	2	7	8	1.0	0.012-0.047
Grapes	2	5	10	1.4	0.012-0.047
Grasses Grown For Seed	1.5	2	3	0.8 (based on hay)	-
Leafy Vegetable (head and leaf lettuce, endive, mustard green)	2 - foliar 2.2 - soil broadcast	5 4	6 Not specified	1.1	0.012-0.047
Nuts (almond, chestnut, pecan, pistachio, walnut, etc.), foliar or dormant/delayed	5	4	15	2.5 (pecans)	0.047-0.12
Nuts (almond, chestnut, pecan, walnut), foliar in CA	1 lb ai/100 gal	Not specified	Not specified	Not specified	0.047-0.12
Ornamental	2.2 or 2% solution	-	-	1.5	0.023
Oyster beds (SLN only)	10	Not specified	Not specified	-	-
Peanut	2	5	8	0.8	0.012-0.047
Pome fruit	3	8	15	1.2 (based on apples)	0.012-0.07
Potatoes & Tubers (turnips)	2	6	6	0.8	-
Rangeland/pastures	1	1	1	0.9	-
Rice	1.5	2	4	1.1	-
Right of Way	1.5		3	0.4	-
Sorghum	2	4	6	1.1	-
Stone fruit (apricot, cherry, nectarine, peach, plum/prune), foliar or dormant/delayed	3 4 - CA only	3 foliar & 1 dormant/delayed	14	1.1	0.047-0.12
Stone fruit (apricot, cherry, nectarine, peach, plum/prune), foliar	1 lb ai/100 gal	Not specified	Not specified	Not specified	0.047-0.12
Strawberries	2	5	10	1.4	0.012-0.047
Sugar beets	1.5 to 2	2 to 4	4	1.3	0.012-0.047
Sweet Potatoes	2 foliar 8 lb/100 gal drip	8 foliar Not specified	8 foliar 1.2	1.6 foliar Not specified	0.012-0.047
Sunflower	1.5	2	3	0.7	0.012-0.047
Tobacco	2	4	8	1.1	-
Tree farm	1	-	2	0.7	-
Turf/golf	8-liquids 9-granulars	-	0.8/1000sf	2 to 4	0.047 to 0.25 (lawns) [maximum levels for different products]
Wheat, flax	1.5	2	3	0.8	-
Ants	2%sol	-	-	-	2%sol
Mosquito Control	2	-	-	-	-
Outdoor Banding	2%sol	-	-	-	2%sol

Table5: Application Rates Considered in Risk Assessment					
Crop or Target	Occupational Products				Residential Products lb ai/1000 ft^2 (units may vary)
	lb ai/A/acre (units may vary)	max. apps/season	lb ai/season	Average Rates	
Domestic Animals (e.g., cats/dogs)	Dust 0.2 lb ai/dog Sha. 0.01 lb ai/dog	-	-	-	Dust 0.2 lb ai/dog Sha. 0.01 lb ai/dog
Domestic Animals (e.g., cats/dogs)	1.3 oz/dog collar	-	-	-	1.3 oz/dog collar
Note: In many cases an application rate per area (e.g., 1000 ft^2) is provided but a 1 to 2 % ai w/v solution can be used to make similar applications where volume outputs are difficult to regulate (i.e., handheld equipment where area treated is difficult to define).					

4.2 Dietary Risk Assessment

The Product and Residue Chemistry Chapters (D283328; May 30, 2002) and the Dietary Exposure Analysis (D281419; April 28, 2002) were prepared by Felecia Fort. Potential exposure to residues of carbaryl in the diet occurs through food and water. Carbaryl is used late in the season at maximal seasonal rates of 6-12 lb ai/acre. [Note: There is also a section 3 registration that allows use on citrus up to 16 lb ai/acre only in the state of California.] Post harvest intervals (PHIs) range from 1-29 days but most are one week or less. The qualitative nature of carbaryl residues in plants and animals is adequately understood. The carbaryl residue to be regulated in plants is carbaryl per se. The residues of concern in meat and milk are the free and conjugated forms of carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, and 5-methoxy-6-hydroxy carbaryl. Adequate Pesticide Data Program (PDP) and Food and Drug Administration (FDA) monitoring residue data are available for the vast majority (>80%) of commodities. Detectable residues were found in 31 of 42 crops. In field trials, residues were less than the Limit of Quantitation (LOQ) in 5 crops but were quantifiable in all other raw agricultural commodities (RACs).

The dietary exposure assessment is a Tier 3/4 assessment, which is the most highly refined assessment that can be conducted at this time. HED has provided anticipated residues (ARs) for carbaryl based on USDA PDP and FDA monitoring data, along with field trial data, for many commodities. In addition, separate acute assessments were conducted incorporating the results of the Carbamate Market Basket Survey (CMBS)[4].

[4] At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. The primary concern was rubbing sampled commodities during the rinsing process except for broccoli and tomato because this created a potential for residue loss from the mechanical action associated with rubbing. A separate assessment was also completed using other sources of high quality residue data (e.g., PDP) for comparative purposes to more completely inform the risk management process.

Carbaryl and its degradate 1-naphthol are fairly mobile but are not likely to persist or accumulate in the environment. Available non-targeted monitoring studies were of limited utility in developing estimated environmental concentrations (EECs) of carbaryl in water. Therefore, screening models were utilized in assessing carbaryl residues in drinking water (see Section 4.3 below for more details).

Section 4.2.1: Residue Profile provides information on the residue data used to complete the dietary risk assessments. *Section 4.2.2: Acute Dietary Risk Assessment* presents the acute assessment with and without the CMBS data. *Section 4.2.3: Chronic Dietary Risk Assessment* presents the results for this duration of exposure. *Section 4.2.4: Cancer Dietary Risk Assessment* presents cancer risks. *Section 4.2.5 Characterization/Uncertainties of the Risk Estimates* provides information that should be considered along with the numerical results of this assessment.

4.2.1 Residue Profile

Tolerances for residues of carbaryl are currently expressed in terms of carbaryl (1-naphthyl N-methylcarbamate), including its hydrolysis product 1-naphthol, calculated as carbaryl, for most raw crop commodities (RACs) [40 CFR §180.169(a)]. The established tolerances for residues in/on pineapples, pome fruits, avocados, and fresh dill are expressed in terms of carbaryl *per se* [40 CFR §180.169(d) and (e)]. Tolerances for residues in livestock commodities are expressed as carbaryl, including its metabolites 1-naphthol (naphthyl sulfate), 5,6-dihydrodihydroxy carbaryl, and 5,6-dihydrodihydroxy naphthol, calculated as carbaryl [40 CFR §180.169(b) and (c)]. A tolerance for residues in pineapple bran is expressed in terms of carbaryl *per se* [40 CFR §186.550]. The HED Metabolism Committee concluded that the carbaryl residue to be regulated in plants is carbaryl *per se* (DP Barcode D221979, S. Hummel, 2/8/96). The Committee also concluded that carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl, 5-methoxy-6-hydroxy carbaryl and all residues which can be hydrolyzed to carbaryl, 5,6-dihydro-5,6-dihydroxy carbaryl and 5-methoxy-6-hydroxy carbaryl under acidic conditions should be included in the tolerance expression and risk assessment for all endpoints of dietary concern for livestock commodities only. (C. Olinger, D255855, 6/21/99). An interim tolerance of 0.5 ppm has been established for carbaryl and its 1-naphthol metabolite in eggs [40 CFR §180.319]. Tolerances of 2 ppm and 10 ppm have been established for residues of carbaryl in pineapples and bananas, respectively. The registrant intends to support the tolerances for residues of carbaryl in/on these commodities as import tolerances.

Currently, the Codex MRLs and U.S. tolerances are not compatible because the U.S. tolerance expression includes metabolites. Once the U.S. tolerance definition is amended, it will be compatible with the definition for Codex MRLs. The Metabolism Committee has also recommended that the tolerance expression for livestock commodities include the free and conjugated forms of carbaryl; 5,6-dihydro-5,6-dihydroxy carbaryl; and 5-methoxy-6-hydroxy carbaryl. The Codex MRLs and U.S. tolerances cannot be made compatible for livestock commodities with respect to the tolerance definition.

The reregistration requirements for plant and livestock metabolism are fulfilled. Acceptable metabolism studies depicting the qualitative nature of residues in lettuce, radish, soybeans, ruminants and poultry have been submitted and evaluated. For the purpose of reregistration, adequate magnitude of the residue data are available on the following crops: alfalfa, almond, asparagus, beans (dried and succulent), blueberry, broccoli, cabbage, celery, cherry, citrus fruits, clover, corn (sweet and field), cucurbits (cantaloupes, cucumbers and squash), cranberry, flax, grape, head and leaf lettuce, mustard greens, okra, peanut, peas (dried and succulent), pecan, pepper, pistachio, pome fruits, potato, prickly pear cactus, raspberry, rice, sorghum, soybean, spinach, stone fruits, strawberry, sunflower, sweet potato, tobacco, tomato, walnut. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted. Carbaryl residues were <LOQ in/on sweet potato, sugar beets, corn grain, flax seed, and peanuts. Quantifiable residues were detected in all other RACs. For a given crop, residue levels were quite variable overall, probably owing to climactic variations, but were generally consistent within any specific field trial location. There are data gaps which are listed in *Section 8.0: Data Needs/Label Requirements*.

Adequate PDP monitoring data were available for the commodities potatoes, carrots, sweet potato, celery, spinach, lettuce (head), broccoli, succulent peas (processed) , succulent beans, soybean, tomatoes, cantaloupe, winter squash, orange, orange juice, apple, apple juice, pear, peach, wheat, sweet corn, banana, grape, grape juice and milk. FDA monitoring data were used for the commodities, lettuce (leaf), cabbage, eggplant, succulent peas (fresh), non-bell pepper, bell pepper, cucumber, watermelon, summer squash, cherries, raspberry, blueberry,asparagus, cranberries, pineapple, and strawberry. Monitoring data were translated to similar crops when possible, generally according to the HED SOP 99.3 "Translation of Monitoring Data". Monitoring data from the years 1994 through 1998 (PDP) and the years 1992 through 1998 (FDA) were considered. Field trial data were used for the commodities, garden beets, turnips, mustards, dried beans, almonds, pecans, walnuts, field corn grain, rice, flax seed, okra, olive, peanuts, pistachio, sugar beets, dried peas, and sunflower.

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEM™), which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. In this assessment, CFSII data from 1994 to 1998 were also considered along with the earlier data for comparative purposes. Routinely, the 1989 to 1992 data are used for risk assessments; however, the Aventis Crop Science commented that the 1994 to 1998 data should also be considered. The Agency completed the analysis using both sets of consumption data in response to this comment. In these surveys, both 3-day mean consumption and single-day consumption information were recorded for 22 demographic and socio-economic subpopulations including infants, children, and nursing women. For acute dietary risk assessments, the entire distribution of consumption events for individuals is multiplied by a randomly selected distribution of residues (probabilistic analysis, referred to as "Monte Carlo") to obtain a distribution of exposures in mg/kg/day. For chronic dietary risk assessments, the 3-day average for each subpopulation is combined with average residues in commodities to determine average exposures (mg/kg/day).

Anticipated residue estimates were prepared using USDA Pesticide Data Program (PDP) data, if available. Alternatively, FDA surveillance monitoring data from the years 1992-98 were used if sufficient samples were available. Data from crop field trials were used if there were insufficient PDP or FDA monitoring data. In addition, separate acute assessments were conducted incorporating the results of the CMBS as described above (i.e., rubbing fruit may reduce residues, use of other high quality data leads to a more informed risk management decision).

The Biological and Economic Analysis Division (BEAD) provided information (F. Hernandez, 7/21/98) on the percent crop treated (%CT). For the chronic analysis, the weighted average %CT was incorporated; for the acute analysis, the estimated maximum %CT was used when appropriate. In acute analyses (except blended commodities) the adjustment for %CT is incorporated in the residue distribution files (RDFs) via addition of zero residue values corresponding to the % of crop not treated. For blended/not furthered processed commodities where monitoring data are available, the entire distribution of monitoring data with no further adjustment for %CT were used. For blended/processed commodities where monitoring data are available and for all blended commodities where field trial data were used, %CT is incorporated into a point estimate. For the chronic analyses, the %CT is listed as Adjustment Factor 2 in the DEEM analysis. One half the weighted average of the limits of detection was used in the dietary assessment for all treated non-detectable residues. Detectable residues from composite monitoring data for non-blended food forms were used to generate residue values in single units using the methods described in the H. Allender paper dated 5/26/99 "Statistical methods for Use of Composite Data in Acute Dietary Risk Assessment." The "decomposited" residues were then included in residue distribution files (RDF) for the probabilistic analysis. BEAD-supplied percent crop treated data were incorporated into the anticipated residue or residue distribution file when appropriate. [Note: Single serving peach PDP data were used for non-blended peach food forms instead of data that had been previously decomposited (Allender method).]

A separate dietary assessment was conducted utilizing the CMBS results. The CMBS Task Force conducted a year long, national survey of carbamate residues on selected food commodities purchased at grocery stores. Residue data from a market basket survey are considered close approximations to residues potentially found at most 'dinner plates'. These data are generally considered the most appropriate survey type for use in pesticide risk and exposure assessment. The CMBS collected up to 400 single-serve samples of 8 different crops (apple, banana, broccoli, grape, lettuce, orange, peach and tomato). These data were used in the acute dietary analysis directly via RDFs incorporating %CT for all food forms which are considered to be partially or not blended. For blended commodities, the entire distribution of data with no further adjustment for % CT was used. If CMBS data were not available, then PDP or FDA monitoring or field trial data were used. CMBS data were translated to similar commodities when feasible; however, if PDP monitoring data were available for the processed commodity, then CMBS data were not translated (i.e., PDP orange juice data were used instead of CMBS data for oranges). The dietary risk assessments were completed with and without the results of the CMBS for comparative purposes, again as described above (i.e., rubbing fruit may reduce residues, use of other high quality data leads to a more informed risk management decision).

Most of the carbaryl processing factors were obtained from processing studies submitted by the registrant. The rice processing factors were from a review by Thurston Morton (D216242, 9/17/98).

4.2.2 Acute Dietary Risk Assessment

The following equations were used to calculate dietary exposure and non-cancer risk for carbaryl.

Dietary exposure (mg/kg/day) = consumption x residue

$$\text{Dietary risk (\% PAD)} = \frac{\text{dietary exposure (mg/kg/day)}}{\text{population adjusted dose (mg/kg/day)}} \times 100$$

The population adjusted dose (PAD) is the adjusted RfD reflecting the retention or removal of the FQPA safety factor. For carbaryl, the FQPA safety factor has been reduced to 1x. The resulting acute PAD (aPAD) and chronic PAD (cPAD) are both 0.01 mg/kg/day. The doses and endpoints selected by the HIARC for these risk assessments are discussed in more detail in *Section 3.3: Dose Response Assessment* above.

For this Tier 3/4 Assessment, estimated acute dietary exposure at the 99.9^{th} percentile of exposure exceeds HED's level of concern without incorporating the CMBS results for all infants and children (1-6 years) based on 1989 to 1992 CFSII data (Table 6). The highest exposed subpopulation incorporating all commodities using PDP and FDA monitoring data without CMBS data was all infants at 133 percent of the aPAD while children (1-6 years) were at 110 percent of the aPAD. The same general trend applied when the 1994 to 1998 CFSII data were considered but risks were actually higher for all subpopulations (infants at 134 percent of the aPAD and children (1 to 6 years old) at 138 percent of the aPAD). The Agency routinely uses the 1989 to 1992 CFSII data for risk assessments. However, Aventis Crop Science commented that 1994 to 1998 CFSII data should also be considered so the Agency used both for comparative purposes. Prior to the calculation of these risk estimates, residues in poultry were the key contributors to the risks for various populations. Since then, Aventis Crop Science has indicated that poultry uses will be deleted (i.e., poultry uses were not considered in this assessment). As such, it appears that consumption of apples and peaches are the critical contributors to acute dietary risks. A sensitivity analysis was conducted using 1989 to 1992 CFSII by eliminating these crops and crops where no detectable residues were found (Table 7). This analysis showed that risk estimates were not significantly affected by assuming zero in place of ½ LOD on samples reported as not detectable. Eliminating apples reduced exposures of children (1-6 years) to 82 percent of the aPAD but did not significantly impact the risks for all infants which were still at 118 percent of the aPAD. Eliminating peaches had the greatest impact. Risks to children (1-6 years) still exceeded 100 percent of the aPAD at 102 percent. Risks for all infants, however, were reduced to 72 percent of the aPAD.

Table 6: Results of the Carbaryl Acute Dietary Analyses (Market Survey Data Not Included)

Pop. Subgroup	99.9 th Percentile		99 th Percentile		95 th Percentile	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
All Commodities (1989- 92 Consumption Data)						
Gen. Population	0.005989	60	0.001381	14	0.000505	5
All Infants	0.013251	133	0.003683	37	0.000864	9
Children 1 - 6	0.010974	110	0.002552	26	0.001309	13
Children 7 - 12	0.008721	87	0.001644	16	0.000722	7
Females 13 - 50	0.004444	44	0.000918	9	0.000318	3
Males 13-19 yrs	0.003596	36	0.000899	9	0.000428	4

Table 6: Results of the Carbaryl Acute Dietary Analyses (Market Survey Data Not Included)						
Pop. Subgroup	99.9 th Percentile		99 th Percentile		95 th Percentile	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
Males 20+ yrs	0.004223	42	0.000929	9	0.000318	3
Seniors 55+ yrs	0.005789	58	0.001068	11	0.000307	3
All Commodities (1994-98 Consumption Data)						
Gen. Population	0.006150	62	0.001467	15	0.000508	5
All Infants	0.013420	134	0.004027	40	0.000922	9
Children 1 - 6	0.013812	138	0.003282	33	0.001460	15
Children 7 - 12	0.007073	71	0.001473	15	0.000685	7
Females 13 - 50	0.004794	48	0.000997	10	0.000322	3
Males 13-19 yrs	0.005181	52	0.000929	9	0.000420	4
Males 20+ yrs	0.003940	39	0.000922	9	0.000336	3
Seniors 55+ yrs	0.005442	54	0.001003	10	0.000313	3

Table 7. Results of the Carbaryl Sensitivity Analyses.								
Acute - All Commodities at the 99.9th percentile of exposure (Market Basket Survey Data Not Included)								
Pop. Subgroup	All commodities		Eliminating Peaches		Eliminating Apples		Eliminating Commodities with No Detectable Residues	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
Gen. Population	0.005989	60	0.005451	55	0.004943	49	0.005870	59
All Infants	0.013251	133	0.007188	72	0.011784	118	0.012965	130
Children 1 - 6	0.010974	110	0.010164	102	0.008201	82	0.0010765	108
Children 7 - 12	0.008721	87	0.008243	82	0.006867	69	0.008555	86
Females 13 - 50	0.004444	44	0.004262	43	0.003890	39	0.004434	44
Males 13-19 yrs	0.003596	36	0.003535	35	0.003014	30	0.003802	38
Males 20+ yrs	0.004223	42	0.003949	39	0.003575	36	0.004178	42
Seniors 55+ yrs	0.005789	58	0.005456	55	0.005094	51	0.005703	57

When the CMBS data were included in the assessment, the acute risk picture for carbaryl significantly changed as risks for all population subgroups considered were less than 100 percent of the aPAD (Table 8). If 1989-1992 CFSII data are used, all infants and children (1-6 years) again had the highest associated risk levels at 73 percent and 75 percent of the aPAD, respectively. For 1994-1998 CFSII data, all infants and children (1-6 years) also have the highest risks at 81 and 93 percent of the aPAD, respectively. At the present time, information from the industry-sponsored Carbamate Market Basket Survey has been approved for use in dietary risk assessments with appropriate characterization of uncertainties associated with the conduct of the study. Hence, the use of these data in this assessment should be considered with associated caveats (e.g., rubbing fruit).

Table 8. Results of the Carbaryl Acute Dietary Analyses (Market Basket Survey Data Included)						
Pop. Subgroup	99.9 th Percentile		99 th Percentile		95 th Percentile	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
All Commodities (1989-92 Consumption data)						
Gen. Population	0.004580	46	0.001251	13	0.000465	5
All Infants	0.007272	73	0.002875	29	0.000593	6
Children 1 - 6	0.007546	75	0.002283	23	0.001242	12
Children 7 - 12	0.006126	61	0.001355	14	0.000682	7
Females 13 - 50	0.003672	37	0.000863	9	0.000300	3
Males 13-19 yrs	0.002735	27	0.000818	8	0.000409	4
Males 20+ yrs	0.003416	34	0.000842	8	0.000298	3
Seniors 55+ yrs	0.004601	46	0.000921	9	0.000277	3
All Commodities (1994-98 Consumption data)						
Gen. Population	0.004759	48	0.001310	13	0.000468	5
All Infants	0.008051	81	0.002624	26	0.000653	7
Children 1 - 6	0.009274	93	0.002819	28	0.001352	14
Children 7 - 12	0.004831	48	0.001226	12	0.000646	6
Females 13 - 50	0.004194	42	0.000898	9	0.000301	3
Males 13-19 yrs	0.004430	44	0.000876	9	0.000403	4
Males 20+ yrs	0.003254	33	0.000840	8	0.000313	3
Seniors 55+ yrs	0.004427	44	0.000836	8	0.000281	3

4.2.3 Chronic Dietary Risk Assessment

Chronic dietary risks were calculated using the same equations as described above for the acute dietary risk estimates with different inputs appropriate for this exposure duration. Chronic dietary risks are not of concern as risks were <1 percent of the cPAD for all population subgroups considered (Table 9). The Carbamate Market Basket Survey (CMBS) was not used in the calculation of chronic dietary risks because risks were low without considering it and it is not appropriate because it is for single serving data.

Table 9: Results of the Carbaryl Chronic and Cancer Dietary Analyses.				
Chronic				
Pop. Subgroup	1989-92		1994-1998	
	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% cPAD
Gen. Population	0.000032	<1	0.000035	<1
All Infants	0.000054	<1	0.000059	<1
Children 1 - 6 years	0.000057	<1	0.000074	<1
Children 7 - 12 years	0.000036	<1	0.000034	<1
Females 13 - 50 years	0.000026	<1	0.000028	<1
Males 13-19 years	0.000022	<1	0.000026	<1
Males 20+ years	0.000031	<1	0.000032	<1
Seniors 55+	0.000031	<1	0.000030	<1
Cancer				
Gen. Population	0.000032	2.8×10^{-8}	0.000035	$3.04 \text{ X } 10^{-8}$

4.2.4 Cancer Dietary Risk Assessment

The following equations were used to calculate dietary exposure and cancer risk using the Q_1* approach for carbaryl (i.e., linear, low dose extrapolation). Cancer risks were only calculated for the general population.

Dietary exposure (mg/kg/day) = consumption x residue

Dietary cancer risk = average food exposure (mg/kg/day) x Q_1* *(mg/kg/day)*$^{-1}$

Risk estimates above 1×10^{-6} are considered to be of concern. Results indicate a maximum lifetime risk of 2.8×10^{-8} for the general US population if the 1989 to 1992 CFSII data were used. If 1994 to 1998 CFSII data are considered, results are similar for the general U.S. population where cancer risks are 3.04×10^{-8} (Table 9). The Carbamate Market Basket Survey (CMBS) was not used in the calculation of chronic dietary risks.

4.2.5 Characterization/Uncertainties of the Dietary Risk Estimates

- No detectable residues were found in/on several commodities: carrots, chicory, flax seed, horseradish, parsnip, salsify, potato, celery, canned spinach, head lettuce, leaf lettuce, rhubarb, sugarbeets, Swiss chard, brussels sprouts, cabbage, kohlrabi, soybean, corn, banana, peanuts, meat, meat fat, and milk. Sensitivity analyses conducted by eliminating crops where no detectable residues were found showed that risk estimates were not significantly affected by assuming zero in place of ½ LOD on samples reported as not detectable.

- The consumption database routinely used for dietary exposure analysis, CSFII 1989-1992, has a limited number of individuals for the age group infants less than one year old. The USDA has conducted the Supplemental Children's Survey (approximately 5000 children). For comparative purposes, based on comments from the registrant, the CSFII 1994-1998 data have also been used for risk calculations. The trends in the results essentially did not change significantly regardless of which data were used. Risks, in all cases, were slightly higher for all subpopulations using the 1994 to 1998 data.

- The latest cooking and processing factors that were available have been used in the assessment (e.g., processing grapes to raisins, cooking and washing factors for peas, and oil production for peanuts).

- The results of the Critical Exposure Contribution analysis showed that peaches and apples comprised a large percentage of the residues found in the upper percentile tails of the acute exposure distribution for both infants and children (i.e., they were the major risk contributors for children and infant exposure at the upper percentiles).

- Detectable residues from composite monitoring data for non-blended food forms were used to generate residue values in single units using the Allender method. Though there is a statistical basis for using these data, some degree of uncertainty can be associated with this method. [Note: Peaches are a risk driver in this assessment and this analysis is based on single-serving 2000 PDP data instead of data that have been decomposed.]

4.3 Estimated Environmental Concentrations In Water

Dr. Laurence Libelo of the Environmental Fate and Effects Division (EFED) provided an analysis of the available monitoring data and a screening-level assessment using simulation models to estimate the potential Estimated Environmental Concentrations (EECs) of carbaryl in ground and surface water (June 28, 2001). *Section 4.3.1: Environmental Fate Characteristics* provides a summary of the fate characteristics of carbaryl. *Section 4.3.2: Monitoring Data* provides a summary of the monitoring data that were considered in this assessment. *Section 4.3.3: Modeling EECs* presents the EECs used for comparison to the DWLOCs (Drinking Water Levels of Concern) calculated for the aggregate risk assessment (presented in Section 5 below).

4.3.1 Environmental Fate Characteristics

Carbaryl is considered to be moderately mobile and not likely to persist or accumulate in the environment and its degradate, 1-naphthol, appears to be less persistent and mobile than carbaryl itself. Under acidic conditions with limited microbial activity they may persist.

Carbaryl dissipates in the environment by abiotic and microbially mediated degradation. The major degradation products are CO_2 and 1-naphthol, which is further degraded to CO_2. Carbaryl is stable to hydrolysis in acidic conditions but hydrolyzes in neutral ($t_{1/2}$ = 12 days) and alkaline environments (pH=9, $t_{1/2}$ = 3.2 days). Carbaryl is degraded by photolysis in water ($t_{1/2}$ = 21 days). Under aerobic conditions, the compound degrades rapidly by microbial metabolism, with half lives of 4 to 5 days in soil and aquatic environments. In anaerobic environments metabolism is much slower with ½ lives on the order of 2 to 3 months. Carbaryl is moderately mobile in the environment (K_f = 1.7 to 3.5).

The major metabolite of carbaryl degradation by abiotic and microbially mediated processes is 1-naphthol. This degradate represented up to 67 percent of the applied carbaryl in degradation studies. It is also formed in the environment by degradation of napthalene and other polyaromatic hydrocarbons. Only limited information is available for the environmental transport and fate of 1-naphthol. While guideline studies were not specifically submitted for 1-naphthol, open literature data suggest it is less persistent and less mobile than carbaryl.

4.3.2 Monitoring Data

Monitoring data for groundwater and surface water are limited, and targeted data are not available. As reported in the U.S. E.P.A. Pesticides in Groundwater Database, carbaryl was detected in 0.4% of wells sampled. Carbaryl was detected in California (2 out of 1433 wells), Missouri (11 out of 325 wells), New York (69 out of 21027 wells) Rhode Island (13 out of 830 wells) and Virginia (11 out of 138 wells) (Jacoby *et al.*, 1992). The maximum concentration detected was 610 µg/L in NY, though typically the measured concentrations were significantly lower**.**

The EPA STORET database contains 9389 records indicating that analysis was done for carbaryl. Of these, only 4 were reported concentrations above the detection limits. These analyses were all from one well in Cleveland, OK in 1988. The 4 reported concentrations were between 0.8 and 1 ppb.

Carbaryl was detected at greater than the detection limit (0.003 µg/L) in 1.1% of groundwater samples in the USGS NAWQA program. The maximum observed concentration was 0.021 µg/L. Detections were mainly from three settings: wheat (5.8 % of well samples from wheat land use), orchards and vineyards (1.7 % of well samples from orchard and vineyard land use), and urban (1.8% of urban groundwater samples).

A number of field studies have reported detectable carbaryl concentrations in surface waters. Because of limitation in the analytical methods used, there is some question as to the accuracy of carbaryl analysis. Poor analytical methods probably have resulted in lower detection rates and lower concentrations than actually present.

Carbaryl was detected in surface water in 46% of the 36 NAWQA study units between 1991 and 1998. Carbaryl (along with carbofuran) was one of the two most widely detected insecticides. A significant portion of the total carbaryl applied was apparently transported to streams. Out of 5220 surface water samples analyzed, 1082 or about 21 percent were reported as having detections greater than the minimum detection limit (MDL). The maximum reported concentration was 5.5 ug/L. For samples with positive detections the mean concentration was 0.11 µg/L with a standard deviation of 0.43 µg/L. In areas with high agricultural use, the load measured in surface waters was relatively consistent

across the country at about 0.1 percent of the amount used in the basins. Streams draining urban areas showed more frequent detections and higher concentrations than streams draining agricultural or mixed land use areas.

Aventis CropScience submitted interim results of an on-going surface water monitoring study of carbaryl residues in surface water in areas with high agricultural and residential use. In this limited drinking water study, raw water was collected at 16 sites in agricultural areas and four in areas draining suburban areas. Samples at municipal water treatment facilities were collected for 8-12 months. When raw water showed positive detections for carbaryl, finished water samples collected at the same time were analyzed.

In raw water samples from suburban sites, detectable residues in raw water ranged from 0.002 to 0.023 μg/L. In samples from agricultural sites, 9 out of 15 water sources had some detectable level of carbaryl. The detections were generally at low levels with one of about 0.16 μg/L and one of 0.031 μg/L. The rest were below the level of quantitation (<0.03 μ g/L). Samples from finished water were generally lower than raw water though it appears that raw and finished water sampling did not evaluate the same mass of water. The data do not give a good indication of the effectiveness of treatment because samples exiting and entering the treatment plant were different. In several cases, finished water had higher concentrations than raw water and finished water had detectable carbaryl when the raw did not. The highest concentration measured was in finished water (0.16 μ g/L). Raw water sampled at the same time had a much lower concentration (0.010 μ g/L). This illustrates that carbaryl contamination is transient, and that it is unlikely that any sampling would catch the actual peak concentration. That, and the limited number of sites sampled, limit the usefulness of this study. Non-targeted monitoring, such as the NAWQA program has shown that much higher concentrations occur. This study, while useful, does not provide sufficient information to allow estimation of actual peak and mean concentrations that actually occur in all areas or of the effect of treatment.

4.3.3 Modeling EECs

Because of the relatively limited persistence of the compound in the environment, it is highly unlikely that the non-targeted monitoring studies which have been completed detected the maximum concentrations that occur. As a result, the non-targeted monitoring data have been determined to be of limited utility in developing estimated environmental concentrations (EECs) for ecological and human health risk assessment. Therefore, computer modeling was used to estimate surface water and groundwater concentrations that could be expected from normal agricultural use (Table 10). The results of the modeling are supported by the available monitoring data. These results have been characterized as conservative, though not unreasonable estimates of possible concentrations in drinking water.

Surface Water Modeling: Computer modeling with the EPA PRZM3.12 and EXAMS 2.97.7 programs were used to estimate the concentration of carbaryl in surface water. Index reservoir scenarios corrected for Percent Cropped Area (PCA) for representative crops were used. Three different application rates were used in modeling: the maximum allowed on the label for the specific crop, an "average" rate and the maximum rate reported to actually be used. EECs varied greatly depending on the geographic location, crop and application rate. The maximum calculated acute and chronic EECs

(494 ppb and 28 ppb, respectively) resulted from use on citrus in Florida. Modeling "average" and maximum resulting use rates gave EEC values generally 40-60% lower than maximum. The source of drinking water in relation to the EECs must be carefully considered when using these data. In this case, the results for Florida provided the highest estimates, however; in Florida the majority of drinking water is derived from groundwater (>90%) so high surface water concentrations do not necessarily indicate high exposure. As a result, both Florida and the results for Oregon apples have been considered in the aggregate assessment (see Section 5.0 for more information). The EECs for Oregon apples are the next highest values for both the acute and chronic estimates.

Ground Water Modeling: SCI-GROW was used to calculate a groundwater screening exposure value to be used in determining the potential risk to human health. Carbaryl chemical properties are outside the range of values for which SCI-GROW was developed (i.e., aerobic metabolism is faster and its partition coefficient is larger which equates to less leaching than the reference compounds - both factors indicate carbaryl degrades faster). SCI-GROW estimates for groundwater EECs may not predict with complete accuracy, maximum levels because the concentrations calculated are 90 day averages. It is possible; therefore, that groundwater concentration peaks could not be identified. Groundwater levels are anticipated, however, to be more stable over time than surface water concentrations.

Table 10: Carbaryl Drinking Water Estimated Environmental Concentrations (EECs)

Crop	Application Rate Descriptor	Number of Applications per Year	Pounds A.I. per application	Water Acute (ppb) (1 in 10 year peak single day concentration)	Water Chronic (ppb) (1 in 10 year annual average concentration)
Source: Surface Water (PRZM/EXAMs) Sweet Corn (OH) (PCA = 0.46)	Maximum[1]	8	2	37	3.2
	Average[2]	2	3.4	45	2.2
	Maximum[3] Reported	3	1	15	0.9
Source: Surface Water (PRZM/EXAMs) Field Corn (OH) (PCA = 0.46)	Maximum[1]	4	2	30	2.1
	Average[2]	2	1	13	0.6
	Maximum[3] Reported	2	1.5	20	1
Source: Surface Water (PRZM/EXAMs) Apples (OR) (PCA = 0.87)	Maximum[1]	5	2	144	9
	Average[2]	2	1.2	12	0.7
	Maximum[3] Reported	2	1.6	25	1
Source: Surface Water (PRZM/EXAMs) Sugar Beats (MN) (PCA = 0.87)	Maximum[1]	2	1.5	19	2
	Average[2]	1	1.5	12	1.1
	Maximum[3] Reported	1	1.2	9	0.9
Source: Surface Water (PRZM/EXAMs) Citrus (FL) (PCA = 0.87)	Maximum[1]	4	5	494	28
	Average[2]	2	3.4	246	11

Table 10: Carbaryl Drinking Water Estimated Environmental Concentrations (EECs)					
Crop	Application Rate Descriptor	Number of Applications per Year	Pounds A.I. per application	Water Acute (ppb) (1 in 10 year peak single day concentration)	Water Chronic (ppb) (1 in 10 year annual average concentration)
	Maximum[3] Reported	3	4.26	411	16
Source: Surface Water Monitoring				5.5 (Maximum Observed Concentration)	
Source: Groundwater (SCI-GROW)	Maximum[1]	5	4	0.8	0.8
Source: Groundwater (NAWQA Monitoring Data)				0.02	0.02

[1] Maximum application rate on label
[2] Average application rate from Quantitative Usage Analysis for Carbaryl, prepared July 21, 1998 by Frank Hernandez, OPP/BEAD
[3] Maximum rate of application reported in DOANES survey data

4.4 Residential Risk Assessment

The residential risk assessment addresses exposures that individuals receive through their use of consumer products that contain carbaryl and those exposures one could receive from frequenting areas that have been previously treated with carbaryl such as a home lawn, a garden, or a golf course. Carbaryl can also be applied in wide area treatments such as on oyster beds or as a mosquito adulticide. These exposures have also been addressed in this assessment. The Occupational and Residential Exposure Assessment (D281418) was prepared by Jeff Dawson with the exception of the tobacco assessment completed by Dr. Virginia Dobozy. The document D281418 contains detailed descriptions of the data used, methods, and risks calculated for each scenario. Please refer to that document for more specific
information.

Section 4.4.1: Home Uses provides more specific information pertaining to how carbaryl consumer products are used in addition to the information presented above in *Section 4.1: Summary of Registered Uses* as it applied more directly to the residential risk assessment. *Section 4.4.2: Residential Handler Risk Assessment* describes the data, methods, and risk results (both cancer and noncancer) associated with the use of consumer products which contain carbaryl. *Section 4.4.3: Residential Postapplication Risk Assessment* describes the data, methods, and risk results associated with exposures to the general population including adults, infants, and youth-aged children that occur from frequenting treated areas. *Section 4.4.4: Residential Risk Characterization* provides information pertaining to the quality of the assessment including data used, uncertainties with the methods, and any other information that might be used to describe the quality of the results. *Section 4.4.5: Risks Associated With Use In Tobacco* describes how risks were calculated for smokers who may consume carbaryl treated tobacco in their cigarettes. *Section 4.4.6: Other Residential Uses* characterizes other potential sources of exposure outside of those quantitatively described in this assessment.

4.4.1 Home Uses

Carbaryl is a widely-used consumer product. Available products include liquids, wettable powders, and dusts for insect control on fruits, vegetables, ornamentals, and lawns. Products for flea control on pets are also available. Some of the equipment used in application includes dust shaker cans, garden hose end sprayers, trigger sprayers, low pressure handwands, belly grinders, push-type spreaders, aerosol cans, and pet collars. In addition to the information presented in *Section 4.1: Summary Of Registered Uses*, Aventis Crop Science at the time of the September 24, 1998 SMART Meeting also presented the following information that is key to interpreting the residential risk assessment. Carbaryl accounted for approximately 9 percent of the total residential insecticide market and was ranked fourth on the list behind the pyrethroids, chlorpyrifos, and diazinon. In addition, the registrant also presented the following:

- According to the registrant, insect control on vegetables (~58% of users), annuals (~50% of users), lawns (~35% of users), trees/shrubs (~34% of users) account for the majority of homeowner uses for carbaryl. Pet uses also accounted for ~13 percent of users.

- The annual frequency of use, for all crops/targets, was reported to be at the 60th percentile for 1 to 2 times per year and at the 84th percentile for 5 times per year.

- Aphids, ants, fire ants, fleas, and slugs/snails are predominant pests controlled by residential carbaryl users (~30 down to 15% of users, respectively).

- Most (75%) of vegetable gardens treated with carbaryl are <800 ft^2 but ~8 percent are between 800 and 1500 ft^2, ~9 percent are between 1500 and 5000 ft^2, and ~6 percent are greater than 5000 ft^2. Tomatoes, peppers, cucumbers, beans, and fruit trees represent the most treated garden plants.

- Most (82%) of flower gardens treated with carbaryl are <500 ft^2 but ~10 percent are between 500 and 1200 ft^2, and ~8 percent are greater than 1200 ft^2. Roses, shrubs, and certain annuals represent the most treated flowering/ornamental plants.

- Dusts (65%) and liquid concentrates (25%) account for most carbaryl sales in the residential annual market of 2 million pounds per year.

4.4.2 Residential Handler Risk Assessment

The anticipated use patterns and current labeling indicate 17 major residential exposure scenarios, based on the types of equipment and techniques, in which homeowners can be exposed to carbaryl during the application process. The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios. For most scenarios, multiple uses and application rates were considered for a total of 54 distinct combinations. The 17 major scenarios include:

(1) Garden Uses: Ready-to-use Trigger Sprayer;
(2) Garden Uses: Ornamental Duster;
(3) Garden Uses: Hose-end Sprayer;
(4) Garden Uses: Low Pressure Handwand;
(5) Tree/ornamental Uses: Low Pressure Handwand;
(6) Tree/ornamental Uses: Hose-end Sprayer;
(7) Garden Uses: Backpack Sprayer;
(8) Lawncare Liquid Uses: Hose-end Sprayer;
(9) Pet (Dog and Cat) Uses: Dusting;
(10) Pet (Dog and Cat) Uses: Liquid Application;
(11) Lawncare Granular and Bait Uses: Belly Grinder;
(12) Lawncare Granular and Bait Uses: Push-type Spreader;
(13) Ornamental and Garden Uses: Granulars and Baits By Hand;
(14) Various Pest Uses: Aerosol Cans;
(15) Pet (Dog and Cat) Uses: Collars;
(16) Garden and Ornamental Uses: Sprinkler Can; and
(17) Garden and Ornamental Uses: Paint-on.

Data and Assumptions A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessments, as described below.

- The unit exposure values used in this assessment were based on three carbaryl-specific residential handler studies which quantified exposures during pet treatments with a dust; applications to gardens using a ready-to-use trigger sprayer, a dust, a hose-end sprayer, and a low-pressure handwand; and during applications to trees using a low-pressure handwand and a hose-end sprayer. Two other studies completed by the Outdoor Residential Exposure Task Force (ORETF) and the Pesticide Handlers Exposure Database (Version 1.1 August 1998) (PHED)[5] were also used as sources of surrogate information. [Note to Risk Managers: There is no data compensation issue associated with the use of the ORETF data in the carbaryl risk assessment because Aventis CropScience, the registrant for carbaryl, is a member of the ORETF]. Summaries of the five studies are included in the Occupational and Residential Risk Assessment (D281418). These studies are all considered to be of high quality. The quality of the data in PHED varies from scenarios that meet study guideline requirements to others where a limited number of poor quality data points are available. However, in all cases, the data used represent the best available for the scenario. The PHED unit exposure values range between geometric mean and median of available exposure data. When data from other studies were used, the

[5] PHED is a generic database, which includes the results of over 100 exposure studies, developed by US EPA, Pest Management Regulatory Agency/ Health Canada and the California Department of Pesticide Regulation, in cooperation with the pesticide industry.

appropriate statistical measure of central tendency was used. Central tendency values, coupled with other inputs used by HED, are thought to result in conservative, deterministic estimates of risk. For pet collars only, a scenario from the *SOPs For Residential Exposure Assessment* not based on monitoring data was used to calculate exposures. The factors derived from the SOPs are generally thought to be conservative.

- Average body weight of adult handlers is assumed to be 70 kg because the toxicology endpoint values used for the risk assessments are appropriate for average adult body weight representing the general population. No specific effects were observed consistently in the toxicology studies to indicate an increased sensitivity of one gender over another.

- Homeowner handler assessments were completed based on individuals wearing shorts and short-sleeved shirts.

- Homeowner handlers are expected to complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application;

- Label maximum use rates and use information specific to residential products served as the basis for the risk calculations. If additional information, such as average or typical rates, were available, these values were used as well in order to allow risk managers to make a more informed risk management decision. Average application rates were available from the SMART meeting and BEAD's Quantitative Usage Analysis (QUA). These data indicate that in most cases, average application rates differ from maximum application rates by a factor of approximately two. The average application rates identified from the studies conducted by Aventis CropScience were also considered.

- The exposure duration (i.e., years per lifetime) values in the cancer risk assessment are consistent with those used for other chemicals (i.e., 50 years with home-use chemicals and 70 year lifetime). Cancer risks were calculated assuming one exposure per year. In addition the number of days of exposure per year which could occur under the ceiling established by an acceptable risk level of $1x10^{-6}$ were also calculated. These estimates can then be compared to the annual use frequency of 1-2x (60th percentile) and 5x (84th percentile) presented at the SMART meeting. [Note: It is the understanding of the Agency that Aventis Crop Science is also submitting a use analysis based on the Residential Exposure Joint Venture (REJV) survey which could possibly refine these estimates. The Agency will consider these data as appropriate.]

- Calculations were based on scenarios in the home that would reasonably be treated in a day (but would not necessarily take more than an hour or two) such as the size of a lawn, the size of a garden, the amount that can be applied with a piece of equipment, or the number of pets an individual might keep. Based on *Agency Exposure SAC Policy 12: Recommended Revisions To The Standard Operating Procedures For Residential Exposure Assessment*, the daily volumes handled and area treated, excerpted from the policy, used in each residential scenario include (along with corresponding inputs defined from carbaryl studies and the SMART meeting for a comparative analysis to allow for a more informed risk management decision):

    - 1 container of each ready-to-use non-pet product including garden dusts, trigger sprayers and aerosol cans (scenarios for 25% and 50% used of the total product volume were also presented for the trigger sprayer and garden dust scenarios to allow for a more informed risk management decision);
    - ½ container of each ready-to-use pet product, including dusts and liquid shampoos;
    - 1 pet collar;
    - 100 gallons of finished spray output for hose-end sprayers;
    - 5 gallons when mixing/loading/applying liquids with a backpack sprayer or a low pressure handwand sprayer; value was also used for sprinkler can applications;
    - 1 gallon of paint-on solution for ornamental/garden uses;
    - 20,000 square feet to represent the surface area treated for broadcast applications to lawns;
    - 1000 square feet as the treatment area for many spot applications in lawns, gardens, and ornamentals (this value used as appropriate when application rates were based on a square foot basis for spot-type treatments); and
    - 5 mounds per day treated for fire ant applications.

- For direct pet treatments, the Residential SOPs were used to define the amount of chemical that can be used to treat single animals, which was then used to calculate total human dose levels. The actual per animal application rates used were ½ of 6 oz. bottle for liquid shampoo (0.5%) and ½ of 4 lb. container for powders (10%).

4.4.2.1 <u>Residential Handler Noncancer Risks</u>

Noncancer risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of the body burden (exposure) to the toxicological endpoint of concern. Short-term dermal MOEs were calculated using a NOAEL of 20.0 mg/kg/day from the 21-day dermal toxicity study in rats with technical material and short-term inhalation MOEs were calculated using a NOAEL of 1 mg/kg/day from the oral developmental neurotoxicity study in rats. Body burden values were determined by first calculating daily exposures using application parameters (i.e., rate and area treated) along with unit exposure levels. Exposures were then normalized by body weight and adjusted for absorption factors (100 percent for both dermal and inhalation) as appropriate to calculate average daily dose levels (i.e., body burdens) as illustrated in equation below.

Daily Exposure (mg ai/day) =

Unit Exposure (mg ai/lb ai) x Application Rate (lb ai/A) x Daily Acres Treated (A/day)

Where:

Daily Exposure	=	Amount deposited on the surface of the skin that is available for dermal absorption or amount that is inhaled, also referred to as potential dose (mg ai/day);
Unit Exposure	=	Normalized exposure value derived from August 1998 PHED Surrogate Exposure Table and various referenced exposure studies noted above (mg ai/lb ai);
Application Rate	=	Normalized application rate based on a logical unit treatment such as acres or gallons, maximum and typical values are generally used (lb ai/A); and
Daily Acres Treated	=	Normalized application area based on a logical unit treatment such as acres (A/day) or gallons per day can be substituted (gal/day).

The dermal absorption factor of 100 percent based on an absorption study in rats was used for all dermal calculations since no route-to-route conversion was required. No specific inhalation absorption factor is available for carbaryl. Therefore, a factor of 100 percent was used for route-to-route calculations as is done with all pesticides. MOEs were calculated using the following formula.

$$MOE = \frac{NOAEL\ (mg\ ai/kg/day)}{Average\ Daily\ Dose\ (mg\ ai/kg/day)}$$

Where:

MOE	=	Margin of exposure, value used to represent risk or how close a chemical exposure is to being a concern (unitless);
Average Daily Dose	=	The amount as absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day); and
NOAEL	=	No observed adverse effect level or dose level in a toxicity study where no observed adverse effects occurred in the study (mg pesticide active ingredient/kg body weight/day).

A combined (dermal and inhalation) MOE was determined because common toxicity (cholinesterase inhibition) endpoints were used to calculate dermal and inhalation risks for each exposure duration. The following formula was used to calculate total MOE values by combining the route-specific MOEs:

$$MOE_{total} = 1/((1/MOE_a) + (1/MOE_b) + ... (1/MOE_n))$$

Where: MOE_a, MOE_b, and MOE_n represent MOEs for each exposure route of concern

Short-term risks for residential handlers (intermediate-term scenarios are not thought to exist because of the sporadic nature of applications by homeowners) are presented in Table 11. For most scenarios (40 out of 52), risks are not of concern because MOEs exceed the required uncertainty factor of 100. As expected, the scenarios for which MOEs do not meet or exceed 100 have a relatively high unit exposure associated with them or the amount of chemical used over a day is relatively high (based on high application rates and/or high amounts of area treated). The use of dusts in gardens and for pet grooming along with some liquid sprays on ornamentals appear to be the most problematic scenarios. Unlike the occupational handler scenarios, the use of different levels of personal protective clothing and equipment is not considered for residential handlers because of a lack of availability, training, and maintenance. [Note: Scenarios where MOEs are of concern (i.e., <100) for are highlighted in the table.]

TABLE 11 CARBARYL NONCANCER MOEs ATTRIBUTABLE TO COMBINED SHORT-TERM HOMEOWNER HANDLER DERMAL AND INHALATION EXPOSURES

SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSURE FACTORS				DERMAL MOEs	INHALATION MOEs	COMBINED MOEs
			APPL. RATE (lb ai/unit)	BASIS FOR RATE (defines unit treated)	TREATED UNITS	ACTIVE USED (lb ai/event)			
1	Garden: Ready-to-Use Trigger Sprayer (MRID 444598-01)	Vegetables/ Ornamentals	0.003	32 oz bottle 0.126 % (769-977)	0.25	0.00075	34567.9	1393034.8	33730.9
		Vegetables/ Ornamentals	0.003	32 oz bottle 0.126 % (769-977)	0.5	0.0015	17284.0	696517.4	16865.4
		Vegetables/ Ornamentals	0.003	32 oz bottle 0.126 % (769-977)	1	0.003	8642.0	348258.7	8432.7
		Average Study Use Rate	0.012	(lb ai/1000 ft2)	1	0.012	2160.5	87064.7	2108.2
2	Garden/Ornamental Dust (MRID 444598-01)	Vegetables/ Ornamentals	0.4	4 lb bottle 10% (239-1513)	0.25	0.1	**94.6**	804.6	**84.6**
		Vegetables/ Ornamentals	0.4	4 lb bottle 10% (239-1513)	0.5	0.2	**47.3**	402.3	**42.3**
		Vegetables/ Ornamentals	0.4	4 lb bottle 10% (239-1513)	1	0.4	**23.6**	201.1	**21.2**
		Average Study Use Rate	0.079	(lb ai/1000 ft2)	1	0.079	119.7	1018.5	107.1
3	Garden: Hose-End (MRID 444598-01)	General Use (2% soln)	0.02	(lb ai/gal spray applied)	100	2	**20.6**	17500.0	**20.6**
		Perimeter Nuisance Pest	0.19	(lb ai/1000 ft2)	1	0.19	216.7	184210.5	216.5
		Vegetables	0.012	(lb ai/1000 ft2)	1	0.012	3431.4	2916666.7	3427.3
		Vegetables/ Ornamentals	0.023	(lb ai/1000 ft2)	1	0.023	1790.3	1521739.1	1788.2
		Vegetables	0.047	(lb ai/1000 ft2)	1	0.047	876.1	744680.9	875.1
		Average Study Use Rate	0.26	(lb ai/1000 ft2)	1	0.26	158.4	134615.4	158.2
		Fire Ant	0.0075	(lb ai/gal spray)	100	0.75	**54.9**	46666.7	**54.8**
4	Garden: Low Pressure Handwand (MRID 444598-01)	General Use (2% soln)	0.02	(lb ai/gal spray applied)	5	0.1	368.4	77777.8	366.7
		Perimeter Nuisance Pest	0.19	(lb ai/1000 ft2)	1	0.19	193.9	40935.7	193.0
		Vegetables	0.012	(lb ai/1000 ft2)	1	0.012	3070.2	648148.1	3055.7
		Vegetables/ Ornamentals	0.023	(lb ai/1000 ft2)	1	0.023	1601.8	338164.3	1594.3
		Vegetables	0.047	(lb ai/1000 ft2)	1	0.047	783.9	165484.6	780.2
		Average Study Use Rate	0.083	(lb ai/1000 ft2)	1	0.083	443.9	93708.2	441.8
		Fire Ant	0.0075	(lb ai/gal spray)	5	0.0375	982.5	207407.4	977.8

TABLE 11 CARBARYL NONCANCER MOEs ATTRIBUTABLE TO COMBINED SHORT-TERM HOMEOWNER HANDLER DERMAL AND INHALATION EXPOSURES									
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSURE FACTORS				DERMAL MOEs	INHALATION MOEs	COMBINED MOEs
			APPL. RATE (lb ai/unit)	BASIS FOR RATE (defines unit treated)	TREATED UNITS	ACTIVE USED (lb ai/event)			
5	Trees/Ornamentals: Low Pressure Handwand (MRID 445185-01)	Ornamental	0.023	(lb ai/1000 ft2)	1	0.176	1087.0	468227.4	1084.4
		Pome Fruit	0.07	(lb ai/1000 ft2)	1	0.07	357.1	153846.2	356.3
		Nuts/Stone Fruit	0.12	(lb ai/1000 ft2)	1	0.12	208.3	89743.6	207.9
		Citrus	0.176	(lb ai/1000 ft2)	1	0.023	142.0	61188.8	141.7
		Average Study Use Rate	0.0047	(lb ai/gal, 17g ai/4 min at 2GPM)	5	0.024	1063.8	458265.1	1061.4
6	Trees/Ornamentals: Hose End Sprayer (MRID 445185-01)	Ornamental	0.023	(lb ai/1000 ft2)	1	0.176	1560.8	1217391.3	1558.8
		Pome Fruit	0.07	(lb ai/1000 ft2)	1	0.07	512.8	400000.0	512.2
		Nuts/Stone Fruit	0.12	(lb ai/1000 ft2)	1	0.12	299.1	233333.3	298.8
		Citrus	0.176	(lb ai/1000 ft2)	1	0.023	204.0	159090.9	203.7
		Average Study Use Rate	0.005	(lb ai/gal spray)	100	0.5	**71.8**	56000.0	**71.7**
7	Garden: Backpack Sprayer (PHED)	General Use (2% soln)	0.02	(lb ai/gal spray applied)	5	0.1	2745.1	23333.3	2456.1
		Perimeter Nuisance Pest	0.19	(lb ai/1000 ft2)	1	0.19	1444.8	12280.7	1292.7
		Vegetables	0.012	(lb ai/1000 ft2)	1	0.012	22875.8	194444.4	20467.8
		Vegetables/ Ornamentals	0.023	(lb ai/1000 ft2)	1	0.023	11935.2	101449.3	10678.9
		Vegetables	0.047	(lb ai/1000 ft2)	1	0.047	5840.6	49645.4	5225.8
		Average Study Use Rate	0.083	(lb ai/1000 ft2)	1	0.083	3307.3	28112.5	2959.2
		Fire Ant	0.0075	(lb ai/gal spray)	5	0.0375	7320.3	62222.2	6549.7
8	Lawn Care: Hose End Sprayer (MRID 449722-01/ORETF OMA 004)	Lawn (broadcast)	0.25	(lb ai/1000 ft2)	20	5	**25.5**	875.0	**24.7**
		Lawn (spot)	0.25	(lb ai/1000 ft2)	1	0.25	509.1	17500.0	494.7
9	Dusting Dog (MRID 444399-01)	Average Study Use Rate	0.0026	(lb ai/dog)	1	0.0026	163.2	1076.9	141.7
		Dog (10% & ½ of 2 lb)	0.1	(lb ai/dog)	1	0.1	**4.2**	28.0	**3.7**
		Dog (5% & ½ of 2 lb)	0.05	(lb ai/dog)	1	0.05	**8.5**	56.0	**7.4**
10	Dogs: Liquid Application	Dog (0.5% & ½ of 6 oz)	0.001	(lb ai/dog)	1	0.001	14000000.0	No Data	No Data
11	Granular & Baits Lawn Care: Belly Grinder	Lawn (spot)	0.21	(lb ai/1000 ft2)	1	0.21	**60.6**	5376.3	**59.9**
		Lawn (spot)	0.1	(lb ai/1000 ft2)	1	0.1	127.3	11290.3	125.9
12	Granular & Baits Lawn Care: Push-Type Spreader (MRID 449722-01/ORETF OMA 003)	Lawn (broadcast)	0.21	(lb ai/1000 ft2)	20	4.2	490.2	18315.0	477.4
		Lawn (broadcast)	0.1	(lb ai/1000 ft2)	20	2	1029.4	38461.5	1002.6
13	Granulars & Baits By Hand	Ornamentals and Gardens	0.21	(lb ai/1000 ft2)	1	0.21	**15.5**	713.8	**15.2**
14	Aerosol	Various	0.005	(0.5 % ai in soln./1 pt can)	16	0.08	**79.5**	364.6	**65.3**
15	Collar	Dog	0.013	(16 % ai per 1.3 oz collar)	1	0.013	10769230.8	No Data	No Data

TABLE 11 CARBARYL NONCANCER MOEs ATTRIBUTABLE TO COMBINED SHORT-TERM HOMEOWNER HANDLER DERMAL AND INHALATION EXPOSURES									
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSURE FACTORS				DERMAL MOEs	INHALATION MOEs	COMBINED MOEs
			APPL. RATE (lb ai/unit)	BASIS FOR RATE (defines unit treated)	TREATED UNITS	ACTIVE USED (lb ai/event)			
16	Sprinkler Can (Source: Scenario 6)	Ornamentals (2% Soln)	0.02	(2% soln used ad libitum)	5	0.1	359.0	280000.0	358.5
17	Ornamental Paint On	Ornamentals (2% Soln)	0.02	(2% soln used ad libitum)	1	0.02	304.3	12323.9	297.0

4.4.2.2 Residential Handler Cancer Risks

Cancer risks were calculated by comparing the Lifetime Average Daily Dose (LADD) to the Q_1* (8.75 x 10^{-4} $(mg/kg/day)^{-1}$). The LADD was calculated using the equation below.

$$LADD = ADD \times \frac{Treatment\ frequency}{365\ days/year} \times \frac{Working\ duration}{Lifetime}$$

Where:

LADD = Lifetime Average Daily Dose or the amount as absorbed dose received from exposure to a pesticide in a given scenario amortized over a lifetime (mg pesticide active ingredient/kg body weight/day);
ADD = Average Daily Dose or the amount as absorbed dose received from exposure to a pesticide in a given scenario on a daily basis (mg pesticide active ingredient/kg body weight/day) [Note: Represents inhalation and dermal exposure contributions, dermal component has been calculated with a 12.7 % absorption factor defined in a rat study.];
Treatment Frequency = The annual frequency of an application by an individual (days/year);
Working Duration = The amount of a lifetime that an individual spends engaged in a career involving pesticide exposure (years);
Lifetime = The average life expectancy of an individual (years).

Cancer risk was then calculated using the following equation:

$$Risk = LADD \times Q_1^*$$

Where:

Risk = Probability of excess cancer cases over a lifetime (unitless);
Lifetime Average Daily Dose = The amount as absorbed dose received from exposure to a pesticide in a given scenario over a lifetime (mg pesticide active ingredient/kg body weight/day, also referred to as LADD); and
Q_1* = Quantitative dose response factor used for linear, low-dose response cancer risk calculations $(mg/kg/day)^{-1}$.

Table 12 presents the quantitative risks associated with each scenario considered in the assessment. For all but one scenario (i.e., treating dogs with ½ bottle of 10 percent dust - risk is 1.09×10^{-6}), cancer risks are less than 1×10^{-6} (most are in the 10^{-8} or 10^{-10} range) when a single application per year is evaluated. The risk associated with dusting a dog should also be taken in context of the uncertainties associated with cancer risk assessment. In effect, this value is 1×10^{-6}. This table also includes the allowable number of days exposure per year. There are 5 scenarios where 5 days or less of exposure per year is allowable. These results should be considered in conjunction with the use and usage information supplied by the Aventis Crop Science that indicates the 50th percentile annual frequency of use is between 1 and 2 uses per year and that 5 uses per year is at the 84th percentile. As with the noncancer risks, the use of dusts in gardens and for pet grooming along with some liquid sprays on ornamentals appear to be the most problematic scenarios. [Note: The scenario where risks are still of concern (i.e., $>1 \times 10^{-6}$) is highlighted in the table.] Cancer risks appear to be less of concern compared to noncancer risks for all corresponding scenarios.

TABLE 12: CARBARYL CANCER RISKS ATTRIBUTABLE TO COMBINED HOMEOWNER HANDLER DERMAL AND INHALATION EXPOSURES								
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSURE FACTORS				CANCER RISK	ALLOWED DAYS/YR
			APPL. RATE (lb ai/unit)	BASIS FOR RATE (defines unit treated)	TREATED UNITS	ACTIVE USED (lb ai/event)		
1	Garden: Ready-to-Use Trigger Sprayer (MRID 444598-01)	Vegetables/ Ornamentals	0.003	32 oz bottle 0.126 % (769-977)	0.25	0.00075	1.27e-10	>365
		Vegetables/ Ornamentals	0.003	32 oz bottle 0.126 % (769-977)	0.5	0.0015	2.54e-10	>365
		Vegetables/ Ornamentals	0.003	32 oz bottle 0.126 % (769-977)	1	0.003	5.08e-10	>365
		Average Study Use Rate	0.012	(lb ai/1000 ft2)	1	0.012	2.03e-09	>365
2	Garden/Ornamental Dust (MRID 444598-01)	Vegetables/ Ornamentals	0.4	4 lb bottle 10% (239-1513)	0.25	0.1	4.81e-08	21
		Vegetables/ Ornamentals	0.4	4 lb bottle 10% (239-1513)	0.5	0.2	9.62e-08	10
		Vegetables/ Ornamentals	0.4	4 lb bottle 10% (239-1513)	1	0.4	1.92e-07	5
		Average Study Use Rate	0.079	(lb ai/1000 ft2)	1	0.079	3.80e-08	26
3	Garden: Hose-End (MRID 444598-01)	General Use (2% soln)	0.02	(lb ai/gal spray applied)	100	2	2.11e-07	5
		Perimeter Nuisance Pest	0.19	(lb ai/1000 ft2)	1	0.19	2.01e-08	50
		Vegetables	0.012	(lb ai/1000 ft2)	1	0.012	1.27e-09	>365
		Vegetables/ Ornamentals	0.023	(lb ai/1000 ft2)	1	0.023	2.43e-09	>365
		Vegetables	0.047	(lb ai/1000 ft2)	1	0.047	4.97e-09	201
		Average Study Use Rate	0.26	(lb ai/1000 ft2)	1	0.26	2.75e-08	36
		Fire Ant	0.0075	(lb ai/gal spray)	100	0.75	7.93e-08	13
4	Garden: Low Pressure Handwand (MRID 444598-01)	General Use (2% soln)	0.02	(lb ai/gal spray applied)	5	0.1	1.18e-08	85
		Perimeter Nuisance Pest	0.19	(lb ai/1000 ft2)	1	0.19	2.25e-08	45
		Vegetables	0.012	(lb ai/1000 ft2)	1	0.012	1.42e-09	>365
		Vegetables/ Ornamentals	0.023	(lb ai/1000 ft2)	1	0.023	2.72e-09	>365
		Vegetables	0.047	(lb ai/1000 ft2)	1	0.047	5.56e-09	180
		Average Study Use Rate	0.083	(lb ai/1000 ft2)	1	0.083	9.82e-09	102
		Fire Ant	0.0075	(lb ai/gal spray)	5	0.0375	4.44e-09	225

TABLE 12: CARBARYL CANCER RISKS ATTRIBUTABLE TO COMBINED HOMEOWNER HANDLER DERMAL AND INHALATION EXPOSURES								
SCEN.	SCEN. DESCRIPTOR	CROP TYPE OR TARGET	EXPOSURE FACTORS				CANCER RISK	ALLOWED DAYS/YR
			APPL. RATE (lb ai/unit)	BASIS FOR RATE (defines unit treated)	TREATED UNITS	ACTIVE USED (lb ai/event)		
5	Trees/Ornamentals: Low Pressure Handwand (MRID 445185-01)	Ornamental	0.023	(lb ai/1000 ft2)	1	0.176	4.01e-09	250
		Pome Fruit	0.07	(lb ai/1000 ft2)	1	0.07	1.22e-08	82
		Nuts/Stone Fruit	0.12	(lb ai/1000 ft2)	1	0.12	2.09e-08	48
		Citrus	0.176	(lb ai/1000 ft2)	1	0.023	3.06e-08	33
		Average Study Use Rate	0.0047	(lb ai/gal, 17g ai/4 min at 2GPM)	5	0.47	4.09e-09	244
6	Trees/Ornamentals: Hose End Sprayer (MRID 445185-01)	Ornamental	0.023	(lb ai/1000 ft2)	1	0.176	2.79e-09	359
		Pome Fruit	0.07	(lb ai/1000 ft2)	1	0.07	8.49e-09	118
		Nuts/Stone Fruit	0.12	(lb ai/1000 ft2)	1	0.12	1.45e-08	69
		Citrus	0.176	(lb ai/1000 ft2)	1	0.023	2.13e-08	47
		Average Study Use Rate	0.005	(lb ai/gal spray)	100	0.025	6.06e-08	16
7	Garden: Backpack Sprayer (PHED)	General Use (2% soln)	0.02	(lb ai/gal spray applied)	5	0.1	1.66e-09	>365
		Perimeter Nuisance Pest	0.19	(lb ai/1000 ft2)	1	0.19	3.15e-09	317
		Vegetables	0.012	(lb ai/1000 ft2)	1	0.012	1.99e-10	>365
		Vegetables/ Ornamentals	0.023	(lb ai/1000 ft2)	1	0.023	3.81e-10	>365
		Vegetables	0.047	(lb ai/1000 ft2)	1	0.047	7.79e-10	>365
		Average Study Use Rate	0.083	(lb ai/1000 ft2)	1	0.083	1.38e-09	>365
		Fire Ant	0.0075	(lb ai/gal spray)	5	0.0375	6.22e-10	>365
8	Lawn Care: Hose End Sprayer (MRID 449722-01/ORETF OMA 004)	Lawn (broadcast)	0.25	(lb ai/1000 ft2)	20	5	1.73e-07	6
		Lawn (spot)	0.25	(lb ai/1000 ft2)	1	0.25	8.64e-09	116
9	Dusting Dog (MRID 444399-01)	Average Study Use Rate	0.0026	(lb ai/dog)	1	0.0026	2.82e-08	35
		Dog (10% & ½ of 2 lb)	0.1	(lb ai/dog)	1	0.1	**1.09e-06**	**1**
		Dog (5% & ½ of 2 lb)	0.05	(lb ai/dog)	1	0.05	5.43e-07	2
10	Dogs: Liquid Application	Dog (0.5% & ½ of 6 oz)	0.001	(lb ai/dog)	1	0.001	3.11e-13	>365
11	Granular & Baits Lawn Care: Belly Grinder	Lawn (spot)	0.21	(lb ai/1000 ft2)	1	0.21	7.21e-08	14
		Lawn (spot)	0.1	(lb ai/1000 ft2)	1	0.1	3.43e-08	29
12	Granular & Baits Lawn Care: Push-Type Spreader (MRID 449722-01/ ORETF OMA 003)	Lawn (broadcast)	0.21	(lb ai/1000 ft2)	20	4.2	8.97e-09	112
		Lawn (broadcast)	0.1	(lb ai/1000 ft2)	20	2	4.27e-09	234
13	Granulars & Baits By Hand	Ornamentals and Gardens	0.21	(lb ai/1000 ft2)	1	0.21	2.83e-07	4
14	Aerosol	Various	0.005	(0.5 % ai in soln./1 pt can)	16	0.08	5.94e-08	17
15	Collar	Dog	0.013	(16 % ai per 1.3 oz collar)	1	0.013	4.04e-13	>365
16	Sprinkler Can (Source: Scenario 6)	Ornamentals (2% Soln)	0.02	(2% soln used ad libitum)	5	0.1	1.21e-08	82
17	Ornamental Paint On	Ornamentals (2% Soln)	0.02	(2% soln used ad libitum)	1	0.02	1.44e-08	69

4.4.3 Residential Postapplication Risk Assessment

Carbaryl uses are extremely varied and include home gardens, ornamentals, turf (golf courses and lawns) and companion animals (e.g., on dogs and cats). Carbaryl also has more limited uses that were considered including as a mosquito adulticide in residential areas and for Ghost/Mud shrimp control in Washington. As a result, a wide array of individuals of varying ages can potentially be exposed when they do activities in areas that have been previously treated or have contact with treated companion animals. The residential postapplication risk assessment addresses these types of exposures.

The risks from exposure to carbaryl residues postapplication were determined for the following populations:

1) Residential (homeowner) Adults: The following postapplication scenarios were assessed: residential turf (lawncare), residential turf (after mosquito control), swimming/beach activity (oyster bed treatments), golfing, home garden exposure to deciduous trees and home garden exposure to fruiting vegetables. Within each scenario, ranges of exposure were evaluated for different application rates, duration of exposure, and postapplication activities (e.g., weeding, harvesting).

2) Toddlers (3 year-olds): Toddlers were selected as a representative population for turf and companion animal assessments. Exposures from turf were evaluated separately for lawncare uses and after mosquito control. Beach activity (oyster bed treatments) was also evaluated. Separate risk assessments were considered individually and as a total exposure for turf - dermal exposure and hand-to-mouth, object-to-mouth and soil ingestion. For pet uses and the beach play assessments, dermal and hand-to-mouth exposures were considered individually and as a total exposure. A separate assessment was done for toddlers who could potentially ingest carbaryl granules. [Note: Values for this population were used in the aggregate risk calculations for children (1 to 6 years old).]

3) Youth-aged children (ages 10 to 12): children of this age could help with garden maintenance (deciduous trees and fruiting vegetables) and therefore were considered for activities related to fruiting vegetables and fruit trees.

Data and Assumptions A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessments, as described below. The assumptions and factors used in the risk calculations are consistent with current Agency policy for completing residential exposure assessments (i.e., *SOPs For Residential Exposure Assessment* and related documents).

- Several carbaryl-specific studies were used in the development of this assessment including a turf transferable residue (TTR) study conducted in California, Georgia, and Pennsylvania at 8.17 lb ai/acre (MRID 451143-01). This study was conducted using the standard ORETF protocol. The Georgia data were used for the assessment (all were similar). Residue transferability observed in this data was 1.20 percent. The Agricultural Reentry Task Force (ARTF) conducted several dislodgeable foliar residue (DFR) studies with carbaryl. The olive pruning (MRID

451751-02) and cabbage weeding (MRID 451917-01) studies were used in the home garden risk assessments. Aventis Crop Science is a member of the ARTF so there are no data compensation issues associated with the use of these data. All of these carbaryl-specific studies should be considered high quality for risk assessment purposes.

- Two other studies completed by the Washington State Department of Ecology were used for completing the risk assessment for the oyster bed use. These studies provided water and sediment concentration data in Willapa Bay where these applications occur.

- Exposure frequency values used in cancer risk assessments for adults are the same as those used for residential handlers (1 time per year). However, the Agency does believe that there are higher frequency golfers (i.e., average golfers over all ages play 18 rounds year) based on a 1992 report *(Golf Course Operations, Cost of Doing Business/Profitability* by the Center For Golf Course Management). The number of exposure days per year has also been calculated for all postapplication exposure scenarios.

- Several models and published data sources were also used to develop the risk assessment. These include papers related to: deposition from mosquito control by Dukes et al from Florida A&M University and transference of residues from treated pets by Boone et al from Mississippi State University. The Agency's *Standard Operating Procedures For Residential Exposure Assessment* were the primary guidance used for this assessment. Several other models and guidance documents were also used including the Agency's SWIMODEL (for swimmers in Willapa Bay after oyster bed treatments); AgDrift V2.0 (for risks from mosquito control), and the Risk Assessment Guidance For Superfund or RAGS (for dermal exposures during beach play and oyster harvest). Specific information from the mosquito control label and historical information for oyster bed applications were also used to complete the assessments (e.g., droplet spectra requirements to predict deposition from aerial treatments during mosquito control).

- The Agency calculates total exposures to individual chemicals when it is likely that behaviors could occur simultaneously that would lead to the overall dose for the exposed population of concern. The Agency has added together risk values (i.e., MOEs) for different kinds of exposures within the turf (dermal, hand-to-mouth, object-to-mouth, and soil ingestion) and pet scenarios (dermal and hand-to-mouth). These represent the standard set of exposures that are typically added together when chemicals are used on turf or on pets because it is logical they can co-occur.

- Exposures to children playing on treated turf as well as adults on turf (lawncare and golfing) have been addressed using the latest Agency approaches for this scenario including:
    - 5 percent of the application rate has been used to calculate the 0-day residue levels used for defining risks from hand-to-mouth behaviors, measured TTR values are not used because of differences in transferability versus what would be expected during hand-to-mouth behaviors;

- 20 percent of the application rate has been used to calculate the 0-day residue levels used for defining risks from object-to-mouth behaviors, measured TTR values are not used because of differences in transferability versus what would be expected during hand-to-mouth behaviors, a higher percent transfer has been used for object-to-mouth behaviors because it involves a teething action believed to be more analogous to DFR/leaf wash sample collection where 20 percent is also used;
- the measured TTR levels quantified in MRID 451143-01 have been used to complete the dermal exposure calculations as the 0-day transferability was > 1 percent of the application rate for the short- and intermediate-term data sources, studies where transferability is less than 1 percent are not used for risk assessment purposes because the transfer coefficients used by the Agency for defining exposures are based on Jazzercize studies in which TTR values were measured by techniques where transferability is generally in the 1 to 5 percent range other than the ORETF roller method where transferability tends to be lower;
- short- and intermediate-term exposures have been calculated because play and mouthing behaviors are assumed to routinely occur daily and for extended periods such as over 30 days, carbaryl residues are also expected to be present based on residue dissipation data (i.e., slow dissipation rate);
- in cases where 0 day residues have been calculated based on application rates (i.e., hand-/object-to-mouth residues and for soil dissipation), dissipation over time measured in the TTR study (i.e., slope of decay curve) has been used to predict TTR and soil levels over time, carbaryl residues were detectable even at 14 days after application (i.e., final sampling interval) at all sites in the TTR studies used in this assessment, at 14 days average residues at the Georgia and Pennsylvania study sites were still orders of magnitude above the quantitation limit, this indicates that predicted residue levels for extended durations should be considered appropriate based on the empirical data (e.g., critical for consideration of intermediate-term exposures);
- the transfer coefficients used, except golfing, are those presented at the 1999 Agency presentation before the FIFRA Science Advisory Panel that have been adopted in routine practice by the Agency;
- transfer coefficients have been adjusted for differences between short- and intermediate-term exposures;
- adult golfers have been assessed using a transfer coefficient of 500 cm^2/hour [Note: The Agency is currently developing a policy on golfer exposures and has used this value in other assessments];
- 3 year old toddlers are expected to weigh 15 kg;
- hand-to-mouth exposures are based on a frequency of 20 events/hour and a surface area per event of 20 cm^2 representing the palmar surfaces of three fingers;
- saliva extraction efficiency is 50 percent meaning that every time the hand goes in the mouth approximately ½ of the residues on the hand are removed;
- object-to-mouth exposures are based on a 25 cm^2 surface area;

- exposure durations are expected to be 2 hours based on information in the Agency's *Exposure Factors Handbook* except for golfers where the exposure duration for an 18 hole round of golf is 4 hours based on a 1992 report *(Golf Course Operations, Cost of Doing Business/Profitability* by the Center For Golf Course Management);
- soil residues are contained in the top centimeter and soil density is 0.67 mL/gram;
- dermal, hand- and object-to-mouth, and soil ingestion are added together to represent an overall risk from exposure to turf while granular ingestion is considered to be a much more episodic behavior and is considered separately by the Agency; and
- children of various ages down to the very young (e.g., 4 or 5 years old) are currently playing golf, the Agency recognizes that age may impact exposures because of changes in behavior and skin surface area to body weight ratios but has not yet developed a quantitative approach for calculating their risks.

- Exposures to children and adults working in home gardens have been addressed using the latest Agency approaches for this scenario including:
  - youth-aged children are considered along with adults;
  - 12 year old youth are expected to weigh 39.1 kg;
  - exposure durations are expected to be 40 minutes;
  - Pre-Harvest Intervals (PHIs) are less than 7 days for most crops with some as long as 28 days;
  - transfer coefficients for youth were calculated by adjusting the appropriate adult transfer coefficients by a 50% factor as has been done by the Agency since the inception of the *SOPs For Residential Exposure Assessment*;
  - the updated transfer coefficients specified in Agency policy 003 described above in the occupational risk assessment have been used rather than those currently specified in the SOPs because they represent more refined estimates of exposure for the fruiting vegetable and deciduous tree crop groups, these crop groups have been used in the SOPs to represent home garden exposures;
  - the combination of adjusting transfer coefficients for youth-aged children and using appropriate body weights for the age group results in dose levels that are slightly lower than that of adults in the same activity (the TC reduction and body weight reduction is essentially a 1:1 ratio); and
  - the DFR data used for the assessments are the same as those used in the occupational risk assessment for the selected crop groups.

- Exposures to children after contact with treated pets have been addressed using the latest Agency approaches for this scenario including:
  - only toddlers are considered because their exposures are thought to be highest (i.e., they are considered the highest exposed population by the Agency);

    - an equilibrium approach based on a single child "hug" of the treated animal is used to assess dermal exposure as described in the 1999 Agency SAP Overview document (i.e., the skin loads after a single contact with the treated animal and additional contacts don't proportionally add exposures), the surface area of the dermal hug is based on a toddler skin surface area and typical clothing;
    - residue dissipation is 5 percent per day for the shampoo and dust products (based on data from J. Chambers at Mississippi State University on other pet use products);
    - the transferability of residues from fur is 20 percent;
    - the active lifetime of a collar is expected to be 120 days based on label statements which was used by the Agency, a daily emission term from the collar of 0.000290 mg/cm^2/gram ai/day is also based on measured data from Mississippi State University for a pet collar;
    - risks are based on an even loading of residues across the entire surface of a 30 lb dog which has been chosen as a representative animal, the animal surface area was calculated using (12.3*Body Weight (g) $^{0.65}$) from the Agency's 1993 Wildlife Exposure Factors Handbook (i.e., dog surface area of 5986 cm^2);
    - the daily frequency of hand-to-mouth contact with dogs is 40 events per day, in each event, the palmar surface of the hands (i.e., 20cm^2/event) is placed in the mouth of the child contributing to nondietary ingestion exposure; and
    - the Agency is currently in the process of considering revisions in its methodologies for completing risk assessments for pet products, some of the key inputs that are potentially subject to modification include the amount of residues which are transferable from pet fur, defining the number of hand-to-mouth events, and evaluating the emission term for collars.

- There are many likely studies focused on carbaryl in the published literature or available from various governmental Agencies because it is so widely used. For example, the Agency's Office of Research and Development along with other Agencies have funded a project entitled *Pesticide Exposure in Children Living in Agricultural Areas along the United States-Mexico Border Yuma County, Arizona*. Preliminary results of this study indicate that carbaryl residues were identified in the dust of 20 percent of the 152 houses sampled and in approximately 24 percent in 25 samples collected in 6 schools in the same region. At this point, the Agency has not identified any data from the literature or other sources that would alter the conclusions of this risk assessment. As more data become available, the Agency will consider the information in efforts to refine the assessment (i.e., use additional information to alter numeric risk estimates or to characterize existing estimates if warranted). With regard to this specific example, current Agency policy is not to use house dust estimates to calculate risks because of a lack of an appropriate exposure model. Also, in a 1995 study conducted by the Centers For Disease Control (Hill et al) entitled *Pesticide Residues In Urine Of Adults Living In The United States: Reference Range Concentrations*, 1000 adults were monitored via urine collection. One of the analytes measured in that study (1-naphthol) is a potential metabolite of carbaryl as well as of naphthalene and napropamide. This metabolite was identified in 86 percent of the 1000 adults monitored where the mean value was 17 ppb and the 99th percentile was 290 ppb. These values were not used quantitatively in the risk assessment for carbaryl because of the uncertainties associated with them such as the exact contribution of each possible compound to the overall levels and no linked exposure information. The investigators also reported results for (2-naphthol) which is also a metabolite of naphthalene and indicated a common source of exposure because 1-naphthol and 2-naphthol levels were similar based on a Pearson correlation of 0.64 (P=0.0001). The mean for 2-naphthol is 7.2 ppb and the 99^{th} percentile was 54 ppb. The Agency instead considers them a qualitative indicator that exposures in the general population are likely to occur.

- Aventis Crop Science has completed and is in the process of submitting to the Agency a biomonitoring study of individuals in residences following the application by a member of the household to the lawn and either the vegetable garden or ornamental flowers. A biomonitoring study of field workers during harvesting and hand thinning operations in apples and cherries will also be submitted to the Agency. Based on personal communication with Aventis Crop Science scientists, preliminary results from the residential biomonitoring study indicate that the highest percentiles of the distribution of the younger children in the homes were similar to those predicted in the Agency's turf risk assessment for toddlers that are intended to represent the higher percentiles of the exposure distribution. A more detailed analysis will be completed upon submission.

- Aventis Crop Science is also a member of the Residential Exposure Joint Venture which is a group of companies conducting a survey of homeowners to ascertain how consumer pesticide products are used (e.g., rate, frequency, pests, etc.). Also, based on discussions with Aventis Crop Science, an analysis of these data is expected to be submitted which could be used to refine the exposure estimates in this assessment because the amounts of carbaryl used per homeowner application could be refined. Preliminary discussions concerning this survey also indicate Agency estimates are in the range of those observed in the survey.

4.4.3.1 Residential Postapplication Exposure and Noncancer Risks

Two different types of noncancer risk calculations were required based on expected exposure durations, i.e., short-term ($\leq$30 days) and intermediate-term (30 days up to several months). Intermediate-term risks were calculated in a postapplication situation, when they were not for residential handlers, because residue dissipation data demonstrated that carbaryl residues persist over that time and it is clear that the behaviors considered as the basis for this assessment can occur routinely over extended periods of time thus creating a potential window for exposures (e.g., children playing outside on the grass is expected to be a routine activity). Noncancer risks were calculated using the MOE approach, as described under Section 4.4.2. The toxicological endpoint of concern and target MOE for short-term and intermediate-term dermal exposures is the same as that used for the short-term dermal exposure for residential handlers (i.e., NOAEL of 20 mg/kg from the 21-day dermal toxicity study in the rat and a target MOE of 100). The endpoints of concern and target MOE for short-term and intermediate-term nondietary ingestion exposure were defined in the rat developmental neurotoxicity study and subchronic neurotoxicity studies, respectively (i.e., NOAEL of 1 mg/kg/day defined in both studies with a target MOE of 100).

Several different types of calculations were used in this assessment to reflect the varying age groups, behaviors, data, and activities that were considered. In essence, all can be summarized by saying that a source of some sort (e.g., DFR on leaves) comes in contact with a person as they are doing an activity (e.g., harvesting garden plants). Exposures were then calculated by multiplying the source concentration by some factor (e.g., transfer coefficient for fruit harvesting) and the duration. All of the calculations are explained in detail in the Occupational and Residential Exposure Chapter (281418). Two of the key algorithms are presented below for informational purposes. These represent the predominant types of exposures considered in the postapplication assessment (i.e., dermal and hand-to-mouth).

Dermal exposures were calculated by considering the potential sources of exposure in the environment, which represent the DFRs on garden plants, TTRs on lawns, and transferable residues on treated pets using the following equation. It should also be noted that there are distinct transfer coefficients for different activities (e.g., fruit harvest versus lawncare).

$$DE_{(t)}\ (mg/day) = (TR_{(t)}\ (\mu g/cm^2)\ x\ TC\ (cm^2/hr)\ x\ Hr/Day)/1000\ (\mu g/mg)$$

Where:

DE(t)	=	Daily exposure or amount deposited on the surface of the skin at time (t) attributable for activity in a previously treated area, also referred to as potential dose (mg ai/day);
TR(t)	=	Transferable residues that can either be dislodgeable foliar or turf transferable residue at time (t) where the longest duration is dictated by the decay time observed in the studies ($\mu g/cm^2$);
TC	=	Transfer Coefficient (cm^2/hour); and
Hr/day	=	Exposure duration meant to represent a typical workday (hours).

[Note: For pets, the TC and Hr/day terms are replaced with a onetime "hug" scenario.]

Likewise, nondietary ingestion from hand-to-mouth behaviors also consider the environmental concentrations and the mouthing behaviors of children. The following equation describes how these exposures have been calculated.

$$D = (TR * (SE/100) * SA * Freq * Hr * (1mg/1000\mu g))$$

Where:

D	=	dose from hand-to-mouth activity (mg/day);
TR	=	Transferable Residue where dissipation is based on TTR study and the 0-day value is based on the 5% initial transferability factor ($\mu g/cm^2$);
SE	=	saliva extraction factor (%);
SA	=	surface area of the hands (cm^2);
Freq	=	frequency of hand-to-mouth events (events/hour); and
Hr	=	exposure duration (hours).

The ($TR_{(t)}$) input may represent levels on a single day after application in the case of short-term risk calculations. For intermediate-term calculations, 30-day average concentrations were calculated based on the applicability of the toxicology data (i.e., intermediate-term endpoint is applied to exposures >30 days).

Adult Short-term MOEs only for lawncare (i.e., heavy yardwork) exceed the Agency's level of concern on the day of application (i.e., 43 to 88). For this activity, it takes 1 and 5 days, respectively at the 4 and 8 lb ai/acre application rates,[6] for residues to dissipate to a point where short-term MOEs are ≥100. In all other scenarios considered, short-term MOEs are ≥100 on the day of application. These other scenarios include vegetable gardening, golfing, tending fruit trees. More localized exposures that occur after mosquito control or from exposures associated with oyster bed treatments are also included. Intermediate-term MOEs were calculated using 30 day average exposures and the dissipation rate for carbaryl. In all cases, intermediate-term MOEs are ≥100. Table 13 presents the postapplication MOE values calculated for adults after lawn and home garden applications of carbaryl.

Table 13: Summary of Carbaryl Noncancer Postapplication Residential MOEs For Adults

Scenario	Descriptor	Results		
		Short-term MOE on Day 0	Days Short-term MOE≥ UF	Intermediate-term MOE
Residential Turf (Lawncare)	Max Rate at 4 lb ai/A	88	1	842
	Max Rate at 8 lb ai/A	43	5	412
	Aerial - Mosquito Adulticide 0.016 to 1.0 lb ai/A	3700-231268	0	35463-2216454
	Ground - Mosquito Adulticide 0.016 to 1.0 lb ai/A	7031-439409	0	67380-4211262
Golfing	Max Rate at 4 lb ai/A	1274	0	12297
	Max Rate at 8 lb ai/A	624	0	6021
	Aerial - Mosquito Adulticide 0.016 to 1.0 lb ai/A	53654-3353387	0	517764-32360224
	Ground - Mosquito Adulticide 0.016 to 1.0 lb ai/A	101943-6371435	0	983751-61484426

[6] Maximum rates of 4 to 8 lb ai/acre are specified for different pests. There is one carbaryl label with a turf application rate of 11 lb ai/acre; however, based on the information from the registrant at the SMART meeting and the TTR study (MRID 45334301), the maximum rate is more likely to be 8 lbs ai/acre. In addition, risks exceed HED's level of concern at 8 lbs ai/acre.

Table 13: Summary of Carbaryl Noncancer Postapplication Residential MOEs For Adults				
Scenario	Descriptor	Results		
		Short-term MOE on Day 0	Days Short-term MOE≥ UF	Intermediate-term MOE
Home Garden (Deciduous Tree)	Very Low Exposure (propping)	17373	0	53139
	Low Exposure (irrigation, scout, weed)	1737	0	5314
	High Exposure (harvest, prune, train, tie, thin)	579	0	1771
Home Garden (Fruiting Vegetable)	Low Exposure (irrigation, scout, thin, weed)	1758	0	9468
	Medium Exposure (irrigation, scout)	1256	0	6763
	High Exposure (harvest, prune, stake, tie)	879	0	4734
Oyster Beds	Oyster Harvest	967137	0	2680745
	Swimming	293651	0	No Data

Youth-aged children (10 to 12 years old) were only considered in the home garden scenarios per Agency guidance. Short-term MOEs for these children were similar to those calculated for adults in that they were ≥100 for all of the gardening scenarios considered. Intermediate-term MOEs were calculated using 30 day average exposures and the dissipation rate for carbaryl. In all cases, intermediate-term MOEs are ≥100. Table 14 below summarizes the postapplication MOE values calculated for youth home garden applications of carbaryl.

Table 14: Summary of Carbaryl Noncancer Postapplication Residential MOEs For Youth-Aged Children				
Scenario	Descriptor	Results		
		Short-term MOE on Day 0	Days Short-term MOE≥ UF	Intermediate-term MOE
Home Garden (Deciduous Tree)	Very Low Exposure (propping)	19408	0	59364
	Low Exposure (irrigation, scout, weed)	1941	0	5936
	High Exposure (harvest, prune, train, tie, thin)	647	0	1979

Table 14: Summary of Carbaryl Noncancer Postapplication Residential MOEs For Youth-Aged Children				
Scenario	Descriptor	Results		
		Short-term MOE on Day 0	Days Short-term MOE≥ UF	Intermediate-term MOE
Home Garden (Fruiting Vegetable)	Low Exposure (irrigation, scout, thin, weed)	1964	0	10577
	Medium Exposure (irrigation, scout)	1403	0	7555
	High Exposure (harvest, prune, stake, tie)	982	0	5289

Toddler (3 year old) exposures were considered for a variety of scenarios as described above including play on treated turf, play with treated pets, after mosquito control, and after oyster bed treatments. Ingestion of granules, which is considered a highly episodic event by the Agency is also described below. The results from all scenarios considered are presented below in Table 15.

Short-term MOEs from exposure to treated turf (in products labeled for direct application to turf) were <100 on the day of application for both rates considered (i.e., 4 and 8 lb ai/acre). In fact, short-term MOEs from individual pathways were not ≥100 for any turf scenario considered on the day of application except for the soil ingestion component of the turf assessment which is a very minor contributor to overall exposures. As a reminder, dermal, hand-to-mouth, and object-to-mouth exposures pathways were considered along with soil ingestion. Total short-term MOEs (all pathways) were ≥100 at the lower 4 lb ai/acre application rate 14 days after application and 18 days at the higher 8 lb ai/acre application rate. Dermal and hand-to-mouth exposures were the key contributors while soil ingestion was a minor contributor to the total MOE estimates. Intermediate-term MOEs were calculated using 30 day average exposures and the dissipation rate for carbaryl. For both rates, intermediate-term MOEs were <100. Exposures to toddlers were also considered after application of carbaryl as a mosquito adulticide. The risks are presented along with the turf use risks because the methods are similar except that mosquito control calculations also account for deposition from aerial and ground foggers. Regardless of how applications are made (i.e., by ground or air), both short-term MOEs on the day of application and intermediate-term MOEs were ≥100.

The assessments for pet uses considered dermal and nondietary ingestion exposures and also calculated total MOEs. Short-term MOEs for pet uses were <100 even 30 days after application regardless of whether the formulation used was a dust, liquid or collar. This trend was observed for each separate exposure pathway as well as the total MOE estimates. Hand-to-mouth and dermal exposures are approximately equal contributors to the overall estimates for each product type. The results are similar for the intermediate-term MOEs for each scenario. There is one pet use which is also considered to be a chronic exposure by the Agency. Pet collars are assumed to be worn all of the time so chronic exposure can potentially occur. The chronic MOE for pet collars mirrors the short- and intermediate-term results.

The assessments for beach play for toddlers after oyster bed treatment considered dermal and nondietary ingestion exposures and also calculated total MOEs. Short-term MOEs were >100 even if the highest monitored sediment concentration value from any study available to the Agency was used as the basis for the calculations. The intermediate-term results were similar.

Table 15: Summary of Carbaryl Noncancer Postapplication Residential Aggregate MOEs For Toddlers						
Scenario	Descriptor	Results				
		Short-term MOE on Day 0	Days For Short-term MOE≥ UF	Intermediate-term MOE	Chronic MOE
Pet Treatments	Liquids	2.0	+30	4	NA
	Dusts	0.02	+30	0.04	NA
	Collars	18	+30	18	43
Residential Turf (High Activity)	Max Rate at 4 lb ai/A	11	14	91	NA
	Max Rate at 8 lb ai/A	5	18	45	NA
	Aerial - Mosquito Adulticide 0.016 to 1.0 lb ai/A	448-27983	0	3826-239095	NA
	Ground - Mosquito Adulticide 0.016 to 1.0 lb ai/A	851-53167	0	7269-454280	NA
Oyster Beds	Beach Play	29532	0	81859	NA

Ingestion of carbaryl granules is also a potential source of exposure because children can eat them if they are found in treated lawns or gardens. This scenario is considered to be an episodic in nature. Therefore, acute dietary endpoints are always used. The concentration of carbaryl in granular products ranges generally from 2 to 10 percent. If this information is coupled with the body weight of a toddler (15 kg), the NOAEL of 1 mg/kg/day for short-term assessments (which is also the same value used for the aPAD), and the uncertainty factor of 100 the amount of formulation that can be consumed at the uncertainty factor MOE level can be calculated. The Agency generally presents these results based on the number of carbaryl granules that can be ingested. However, the number of homeowner formulations is extensive and impossible to characterize in that much detail so a general weight estimate is presented. If a 2 percent formulation is ingested, 7.5 mg represents exposure at an MOE of 100 (i.e., 1.6×10^{-5} lb). If a 10 percent formulation is ingested, 1.5 mg represents exposure at an MOE of 100 (i.e., 3.3×10^{-6} lb). For illustrative purposes, if one considers a 2 percent formulation and the density of soil (0.67 mL/gram, many granulars are clay based), only 0.005 mL of formulation would need to be ingested to have a risk concern (i.e., 7.5 mg * 1g/1000mg * 0.67 mL/gram). Note that this volume is orders of magnitude less than a teaspoon of granular formulation (i.e., 0.1% of a teaspoon where a tsp. = 5 mL).

4.4.3.2 <u>Residential Postapplication Exposure and Risks For Cancer</u>

Postapplication cancer risks were calculated for adults only considering the same scenarios. Risks were calculated using a frequency of one exposure per year for 50 years. Cancer risks were calculated using a linear low-dose extrapolation approach in which a LADD is calculated and then compared with a Q_1* (8.75 x 10^{-4} $(mg/kg/day)^{-1}$), as described in Section 4.4.2.2. The number of days of exposure per year under a ceiling limit of cancer risks equal to $1x10^{-6}$ was also calculated.

For all scenarios on turf, cancer risks are in the 10^{-8} range or less on the day of application when a single reentry event per year during lawncare activities is evaluated. For home gardening, golfing or from mosquito control, risks are slightly lower in the 10^{-9} to 10^{-12} range when a single reentry event per year is evaluated on the day of application. Table 16 below summarizes the postapplication risk values calculated for adults after applications of carbaryl. Risk managers should consider these values represent a single reentry day into a treated area over each year of a 50 year lifetime on the day of application and that the Agency lacks data to link the annual frequency of reentry activity to residential applications. As with the residential handler risks above, the Agency calculated the number of exposure days needed to reach a risk level of $1x10^{-6}$ for each scenario on the day of application, values range from 20 to over 365 days per year while most exceed 365 days per year.

Table 16: Summary of Carbaryl Postapplication Residential Cancer Risks For Adults			
Scenario	Descriptor	Results	
		Risk on Day 0	Allowed Days/Year
Residential Turf (Lawncare)	Max Rate at 4 lb ai/A	2.5 x 10^{-8}	40
	Max Rate at 8 lb ai/A	5.1 x 10^{-8}	20
	Aerial - Mosquito Adulticide 0.016 to 1.0 lb ai/A	9.5 x 10^{-12} to 5.9 x 10^{-10}	>365
	Ground - Mosquito Adulticide 0.016 to 1.0 lb ai/A	5.0 x 10^{-12} to 3.1 x 10^{-10}	>365
Golfing	Max Rate at 4 lb ai/A	1.7 x 10^{-9}	>365
	Max Rate at 8 lb ai/A	3.5 x 10^{-9}	287
	Aerial - Mosquito Adulticide 0.016 to 1.0 lb ai/A	6.5 x 10^{-13} to 4.1 x 10^{-11}	>365
	Ground - Mosquito Adulticide 0.016 to 1.0 lb ai/A	3.4 x 10^{-13} to 2.1 x 10^{-11}	>365

Table 16: Summary of Carbaryl Postapplication Residential Cancer Risks For Adults			
Scenario	Descriptor	Results	
		Risk on Day 0	Allowed Days/Year
Home Garden (Deciduous Tree)	Very Low Exposure (propping)	2.5×10^{-10}	>365
	Low Exposure (irrigation, scout, weed)	2.5×10^{-9}	>365
	High Exposure (harvest, prune, train, tie, thin)	7.5×10^{-9}	133
Home Garden (Fruiting Vegetable)	Low Exposure (irrigation, scout, thin, weed)	2.5×10^{-9}	>365
	Medium Exposure (irrigation, scout)	3.5×10^{-9}	289
	High Exposure (harvest, prune, stake, tie)	4.9×10^{-9}	202
Oyster Beds	Oyster Harvest	4.5×10^{-12}	>365
	Swimming	6.1×10^{-12}	>365

4.4.4 Residential Risk Characterization

Characterization of the residential risks is included below for both handlers and for postapplication exposures.

Residential Handlers: The residential handler assessment for carbaryl is complex in that calculations were completed for 52 different equipment and application rate scenarios. Unlike the occupational assessments, only short-term exposures were considered for handlers because homeowner use patterns are not believed by the Agency to lead to intermediate-term exposures because of their sporadic nature. Cancer risks were also calculated using a linear, low-dose extrapolation model (i.e., Q_1*) for typical residential users (1 event/year). Cancer risks were also considered by calculating the number of days exposure that would be required per year to achieve a cancer risk of 1×10^{-6} to illustrate risk levels from another perspective. All totaled, when each type of calculation is considered, 108 different crop/application method calculations were completed for residential handlers.

The data that were used in the in the carbaryl residential handler assessment represent the best data and approaches that are currently available. For most of the major use patterns, carbaryl-specific data or data generated by the *Outdoor Residential Exposure Task Force* were used. These data generally are considered to be high quality by the Agency and the best source of information available for the scenarios where they were used. Carbaryl-specific data were used to address the garden and tree/ornamental scenarios with several types of equipment and formulations including liquid trigger sprayers, dusts, and liquid sprays using low pressure handwand and hose-end sprayers. Carbaryl-specific data were also available for dusting dogs. The ORETF data for hose-end sprayer applications to turf and granular applications to turf were also used to address those scenarios. In the remaining scenarios, the Pesticide Handlers Exposure Database (PHED) was used to develop the unit exposure values. The quality of the data included in PHED vary widely from scenarios that meet guideline requirements for studies to others where a limited number of poor quality datapoints are available. All data that have been used may not be of optimal quality but represent the best available data.

The inputs for application rate and other use/usage information (e.g., area treated and frequency of use) used by the Agency were supported by the available carbaryl labels and information supplied by the Aventis Crop Science at the September 24, 1998 SMART Meeting. It is also very clear that because carbaryl is such as widely used chemical that it is likely every potential exposure scenario has not been captured because of difference in use pattern. As more refined information becomes available on carbaryl use, the Agency will refine its assessment accordingly.

In summary, with respect to residential handler risks, the Agency believes that the values presented in this assessment represent the highest quality results that could be produced given the exposure, use, and toxicology data that are available. However, there are certain elements where additional data are required. For example, it is difficult to ascertain where on a distribution certain input values may fall because the distributional data for exposure, application rates, acres treated and many other parameters are unrefined.

Postapplication: Like the residential handler assessment discussed above, the postapplication residential assessment for carbaryl is also complex in that noncancer MOE calculations were required based on the recently selected endpoints along with cancer risk calculations using a linear, low-dose extrapolation model. Carbaryl residues persist in the environment as indicated in the available DFR and TTR data for periods where intermediate-term as well as short-term noncancer risk estimates are required. Cancer risks were calculated only for adults per current Agency policy.

The general population can be exposed through many different pathways that result from uses on lawns and turf, in gardens, on ornamental plants, and from treated pets. People can also be exposed from mosquito adulticide applications and uses in oyster beds. Carbaryl labels do not currently allow for indoor residential uses (e.g., crack and crevice). Settings where such exposures could occur would include around personal residences and in other areas frequented by the general public including parks, ball fields, and playgrounds. To represent the wide array of possible exposures, the Agency relies on the scenarios that have been defined in the *SOPs For Residential Exposure Assessment* and accompanying documents such as the overview presented to the FIFRA Science Advisory Panel. For turf uses, the Agency considered adults and toddlers (3 year olds) in the assessments. Adult activities included lawncare/maintenance and also golfing. Toddler MOEs were calculated for playing on turf (using exposure data from the Jazzercize model) and also addressed nondietary ingestion (hand-/object-to-mouth and soil ingestion). Exposures from tree and garden uses were evaluated by considering adults and youth-aged children (10 to 12 years old) doing gardening activities such as weeding and harvesting for different crop groups. Transfer coefficients from the fruiting vegetable crop group and the deciduous tree crop group were used, as described in the *SOPs For Residential Exposure Assessment* to represent exposures for these scenarios. MOEs from treated pets were evaluated for toddlers again for whom exposures may occur from dermal contact and hand-to-mouth behavior. Adulticide mosquito applications were considered by first defining how much residues are deposited on the ground after a mosquito control application then using the same methods approaches from the lawncare assessment to address adults doing heavy yardwork or golfing and also children playing on treated turf.

The data that were used in the carbaryl residential postapplication assessment represent the best data and approaches that are currently available. To the extent possible, the Agency has attempted to use carbaryl-specific data such as with the dislodgeable foliar residue (DFR) data used for the garden scenarios and the turf transferable residue (TTR) data used for the dermal component of the turf scenarios. When chemical-specific data were unavailable, the Agency used the current approaches for residential assessment, many of which include recent upgrades to the SOPs. For example, for the toddler hand-to-mouth calculations, the TTR data were not used but a 5 percent transferability factor was applied to calculate residue levels appropriate for this exposure pathway. Another key approach to consider is the use of the dermal hug approach for pet products which was proposed at the September 1999 meeting of the FIFRA Science Advisory Panel. Oyster bed uses were evaluated based on guidance from Superfund and the Agency's SWIMODEL. There are also many embedded uncertainties that should be considered in the interpretation of this assessment such as those associated with the use of Jazzercize and with the nondietary ingestion calculations. Readers should consider these in the interpretation of the overall risk estimates. Readers should also consider the screening nature of the *SOPs For Residential Exposure Assessment* and how additional data could refine the results.

Finally, the Agency believes that the values presented in this assessment represent the highest quality results that could be produced based on the currently available postapplication exposure data. Certainly risk managers and other interested parties should consider the quality of individual inputs when interpreting the results and make decisions accordingly. It is difficult to ascertain where on a distribution the values which have been calculated fall because the distributional data for exposure, residue dissipation and many other parameters are unrefined. The Agency does believe, however, that the risks represent conservative estimates of exposure because maximum application rates are used to define residue levels upon which the calculations are based. Additionally, estimates are thought to be conservative even when measures of central tendency (e.g., most transfer coefficients are thought to be central tendency) are used because values that would be considered to be in the lower percentile aspect of any input parameter have not been used in the calculations.

There are many studies on carbaryl in the published literature or available from various governmental Agencies because it is so widely used that can be used to inform risk managers about the results of the risk assessment. For example, the Agency's Office of Research and Development, along with other Agencies, has funded a project entitled *Pesticide Exposure in Children Living in Agricultural Areas along the United States-Mexico Border Yuma County, Arizona*. Preliminary results of this study indicate that carbaryl residues were identified in the dust of 20 percent of the 152 houses sampled and in approximately 24 percent in 25 samples collected in 6 schools in the same region. Also, in a 1995 study conducted by the Centers For Disease Control entitled *Pesticide Residues In Urine Of Adults Living In*

The United States: Reference Range Concentrations,[7] 1000 adults were monitored via urine collection. One of the analytes measured in that study (1-naphthol) is a potential metabolite of carbaryl as well as of napthalene and napropamide. This metabolite was identified in 86 percent of the 1000 adults monitored where the mean value was 17 ppb and the 99th percentile was 290 ppb. These values were not used quantitatively in the risk assessment for carbaryl because of the associated uncertainties. However, the results from both studies indicate that carbaryl residues are present in areas frequented by the general population and that the scenarios which consider a broad range of exposures are reasonable.

4.4.5 Exposure from the Use of Tobacco

Risks from carbaryl residues contained in tobacco products have been calculated based on a pyrolysis study in tobacco. In assessing exposure through use of tobacco, HED has assumed that the greatest exposure to carbaryl would come from cigarettes. Further, HED has assumed that the average U.S. smoker smokes 15 cigarettes per day.[8] Based on a pyrolysis study submitted by the registrant, residues of carbaryl total approximately 44.58 ppm in combined side-stream and main-stream tobacco smoke (Memorandum from Thurston Morton dated September 29, 1998, D230407). Since this is a composited sample of main-stream and side-stream smoke, it greatly exaggerates the actual exposure to the smoker, whose primary route of exposure is via main-stream smoke. HED further assumes that 100 percent of that inhaled is absorbed (i.e., that none of the residue is exhaled along with the smoke). These assumptions result in an extreme overestimate of actual likely exposure. With the assumptions regarding residue levels and smoking frequency, and assuming an average body weight of 70 kg, HED estimated that exposure to carbaryl will not exceed 0.0096 mg/kg/day [44.58 μg/g cigarette × 1 g/cigarette × 15 cigarettes/day × 1 mg/1000 μg ÷ 70 kg body weight = 0.0096 mg/kg/day].

The short-term inhalation NOAEL is 1 mg/kg/day and is based on an developmental neurotoxicity study in the rat. Based on the inhalation NOAEL, the short-term MOE for carbaryl exposure from the use of tobacco is estimated to be 104 even with the expectation that the calculated risks are an extreme overestimate. The residential target MOE is 100. The Agency has not examined intermediate- or long-term exposure to carbaryl via tobacco due to the severity and quantity of health effects associated with the use of tobacco products.

4.4.6 Other Residential Exposures

This assessment for carbaryl reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines*, the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment*, and the

---

[7] Hill RH *et al* (1995). Pesticide Residues in Urine of Adults Living in the United States: Reference Range Concentrations. Environmental Research 71:99-108.

[8] Pierce JP *et al* (1989). Tobacco Use in 1986 - Methods and Basic Tabulations from Adult Use of Tobacco Survey. U.S. Department of Health and Human Services Publication Number OM90-2004. Office on Smoking and Health, Rockville, Maryland.

Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). The Agency is, however, currently in the process of revising its guidance for completing these types of assessments. Modifications to this assessment shall be incorporated as updated guidance becomes available. This will potentially include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources already not addressed such as from spray drift; residential residue track-in; exposures to farmworker children; and exposures to children in schools.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

Based on the requirements of FQPA, aggregate risk assessments consider combined exposure from food, water and residential uses. Different types of aggregate assessments are required depending upon the use patterns for a chemical, the types of toxic effects associated with it, and the anticipated durations of exposure. A series of aggregate calculations have been completed for carbaryl. *Section 5.1: Calculation of Aggregate Risks and DWLOCs* describes how these values have been determined. *Section 5.2: Acute Dietary Aggregate Risks and DWLOCs* presents the results for the acute dietary only assessment. *Section 5.3: Chronic Dietary Aggregate Risks and DWLOCs* presents the results for the chronic dietary only assessment. *Section 5.4: Short-term Aggregate Risks and DWLOCs* presents the results for the short-term assessment which includes dietary intake and residential exposures. *Section 5.5: Intermediate-term Aggregate Risks and DWLOCs* presents the results for the intermediate-term assessment which includes dietary intake and residential exposures. *Section 5.6: Aggregate Cancer Risks and DWLOCs* presents the results for the cancer assessment that includes dietary intake and residential exposures. *Section 5.7: Summary of Aggregate Risks* provides an overview of the aggregate risk assessment results.

5.1 Calculation of Aggregate Risks and DWLOCs

The Agency has developed several guidance documents describing the mathematical approaches used in calculating aggregate risks, the theoretical basis for these calculations, and the interpretation of the Food Quality Protection Act that requires the Agency to complete these kinds of calculations.[9] The underlying approach, regardless of the calculation type, is the same. The overall risks associated with a specific chemical are determined by its hazard database and its associated uncertainty factors or negligible risks if the concern is cancer. These two elements, combined, are used to define limits for the amount of overall exposures an individual can receive from the chemical. Once these limits have been defined, contributions from different sources of exposure are added together to see if the aggregate limit is exceeded.

The approach used by the Agency for these calculations is to add together estimates for dietary food intake and residential exposure (not used for acute assessment which is food and water

---

[9] There are several aggregate risk guidance documents that address both deterministic and probabilistic risk assessment approaches. The major science policy papers are available at www.EPA.Gov/pesticides. The two key documents used for this assessment are 1) *Updated Interim Guidance For Incorporating Drinking Water Exposure Into Aggregate Risk Assessments* (Stasikowski, 8/1/99) and 2) *HED RARC Format and Risk Characterization Guidance* (12/22/00).

only) then subtract this from the exposure limit to see what portion of the limit is still available, if any. If there is room still left under the limit (i.e., dietary and residential exposures combined do not exceed the exposure limit), then drinking water exposures are considered by calculating DWLOCs (Drinking Water Levels of Concern). If there is no room left under the limit then the Agency knows the overall exposure limit has been exceeded even without considering drinking water intake and no further calculations are completed.

DWLOCs represent the concentration of carbaryl residues in drinking water that cannot be exceeded for aggregate exposures to exceed the overall exposure limit. If appropriate, DWLOCs are calculated by defining what part of the exposure limit has not been taken up from dietary and residential exposures which in turn defines the maximum amount of exposure one can have from drinking water. This can be a very simple calculation such as subtracting acute food exposures from the aPAD or chronic food intake and residential LADD estimates from the Q_1* in a cancer calculation. In some cases it can be more complex such as for the short-term assessment that required using the 1/MOE approach described above in *Section 4.4.2.1: Residential Handler Noncancer Risks* where water and dietary MOEs are added to the equation and compared to the target MOE. The equation was then solved for the water MOE which was in turn used to calculate the maximum drinking water exposure using the short-term oral NOAEL. Maximum allowable drinking water exposure levels were then used to calculate concentrations in water based on standard daily consumption estimates and body weight factors for different subpopulations. Adults were assumed to intake 2 liters of water per day while small children and infants were assumed to intake 1 liter of water per day. Standard body weights were also used (i.e., 10 kg for small children, 60 kg for adult females, and 70 kg for other adult scenarios). The equation used to calculate the DWLOCs is presented below:

$$DWLOC(\mu g/L) = \frac{[\text{water exposure (mg/kg bw/day) x body weight (kg)}]}{[\text{water consumption (L) x } 10^{-3} \text{ mg/}\mu g]}$$

[Note: Water exposure, body weight, and consumption inputs are specific to certain exposure durations, toxicity concerns, and populations so they will vary from assessment to assessment.]

Once the DWLOCs have been calculated they were then compared to the Estimated Environmental Concentrations (EECs) which were defined by the Environmental Fate and Effects Division (*Section 4.3.3: Modeling EECs*, Table 10). Drinking water sources can include surface water or groundwater. EEC values were calculated for both. For surface water, computer modeling with the EPA PRZM3.12 and EXAMS 2.97.7 programs were used to estimate the concentration of carbaryl in surface water. Index reservoir scenarios corrected for Percent Cropped Area (PCA) for representative crops were used. The maximum calculated acute and chronic EECs (494 ppb and 28 ppb, respectively) resulted from use on citrus in Florida. In this case, the results for Florida provided the highest estimates; however, in Florida the majority of drinking water is derived from groundwater (>90%) so high surface water concentrations do not necessarily indicate high exposure. As a result, both Florida and the results for Oregon apples have been considered in the aggregate assessment. The EECs for Oregon apples are the next highest values for both the acute and chronic estimates (144 and 9 ppb, respectively). Carbaryl chemical properties are outside the range of values for which SCI-GROW was developed (i.e., aerobic metabolism is faster and its partition coefficient is larger which equates to less leaching than the reference compounds - both factors indicate carbaryl degrades faster than the reference chemicals). SCI-GROW estimates for groundwater EECs may not predict with complete accuracy, maximum levels because the concentrations calculated are 90 day averages. It is possible; therefore, that groundwater concentration peaks could not be identified. Groundwater levels are anticipated, however, to be more stable than surface water concentrations.

If the EEC is less than the corresponding DWLOC then the Agency has no concerns for aggregate risks for the scenario. If EECs exceed the DWLOC then aggregate risks are of concern. For carbaryl, there were many residential scenarios where the combined MOEs (i.e., combinations of inhalation, dermal and nondietary ingestion as appropriate) exceed the Agency's risk targets making the calculation of DWLOCs and aggregate risks for those scenarios inappropriate because exposure limits have already been exceeded. Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment. However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl survey yet to be submitted to the Agency and the Agency chooses to regulate using the results of the CMBS.

Keeping this in mind, the Agency completed DWLOC and aggregate risk calculations for illustrative purposes using a number of representative exposure scenarios where the residential and dietary risk estimates did not already exceed the Agency's level of concern. For example, an acute assessment with CMBS results included and short-term assessments where residential handler risks weren't already of concern were completed. The Agency also specifically selected some scenarios because they represent major residential uses (e.g., garden dusts) or specialized low exposure scenarios (e.g., mosquito control).

The Agency approach for calculating aggregate risks using different sources of data to create different exposure scenarios for illustrative purposes is consistent with Agency-wide guidance for exposure assessment and risk characterization (e.g., PDP and carbamate market basket survey, various water scenarios, and selected residential scenarios). The Agency takes this approach to allow for more informed risk management decisions that consider as much available data as possible along with the uncertainties associated with those data. For example, it is appropriate to present results based on both PDP and the carbamate market basket survey. PDP data are routinely used in Agency risk assessments and the market basket study is of sufficient quality for incorporation in the risk assessment. However, there are uncertainties associated with the use of each data source (e.g., rubbing of fruit prior to extraction in the carbamate market basket survey which may decrease residue levels as described above in Section 4.2).

5.2 Acute Dietary Aggregate Risks and DWLOCs

The results of the acute aggregate risk assessment are presented below in Table 17. These calculations are based on the use of the Carbamate Market Basket Survey (CMBS). Even with the use of the CMBS, aggregate risks when surface water is the source of drinking water, are still of concern for all infants, children (1 to 6 years old) and children (7 to 12 years old) regardless of whether or not Florida citrus or Oregon apple EECs are used (i.e., surface water is not a major drinking water source in Florida). If Florida citrus data are solely considered, aggregate risks are of concern for all subpopulations. Aggregate risks for all subpopulations are not of concern if groundwater is the source of drinking water. [Note: Most DWLOCs exceed the corresponding EECs for groundwater by an order of magnitude or greater. This should be considered along with the caution that it is possible that Sci-Grow might underestimate groundwater concentrations for carbaryl.]

Table 17: Acute DWLOC Calculations Based on Use of Carbamate Market Basket Survey Results

Population Subgroup	aPAD (mg/kg/day)	Acute Food Exp. 99.9th%tile (mg/kg/day)	Max. Acute Water Exposure (mg/kg/day)	Acute DWLOC (ug/L or ppb)	EECs		
					Surface Water (all PRZM/EXMS)		Ground Water (SciGrow) (ppb)
					FL Citrus (ppb)	OR Apples (ppb)	
All Commodities Using 1989 - 1992 CFSII Consumption Data							
General Population	0.010000	0.004623	0.005377	188	494	144	0.8
All Infants	0.010000	0.007272	0.002728	27	494	144	0.8
Children (1-6 yrs)	0.010000	0.007344	0.002656	27	494	144	0.8
Children (7-12 yrs)	0.010000	0.006238	0.003762	38	494	144	0.8
Females (13-50 yrs)	0.010000	0.003546	0.006454	194	494	144	0.8
Males (13-19 yrs)	0.010000	0.002723	0.007277	255	494	144	0.8
Males (20+ yrs)	0.010000	0.003423	0.006577	230	494	144	0.8
Seniors (55+ yrs)	0.010000	0.004810	0.005190	182	494	144	0.8
All Commodities Using 1994-1998 CFSII Consumption Data							
General Population	0.010000	0.004865	0.005135	180	494	144	0.8
All Infants	0.010000	0.008091	0.001909	19	494	144	0.8
Children (1-6 yrs)	0.010000	0.009481	0.000519	5	494	144	0.8
Children (7-12 yrs)	0.010000	0.004921	0.005079	51	494	144	0.8
Females (13-50 yrs)	0.010000	0.004224	0.005776	173	494	144	0.8
Males (13-19 yrs)	0.010000	0.004515	0.005485	192	494	144	0.8
Males (20+ yrs)	0.010000	0.003359	0.006641	232	494	144	0.8
Seniors (55+ yrs)	0.010000	0.004649	0.005351	187	494	144	0.8

Note: For characterization purposes, the surface water EECs for Florida citrus exceed exposure limits alone, without even considering food intakes, for all populations. Additionally, the surface water EECs for Oregon apples exceed exposure limits alone, without even considering food intakes, for infants and children.

5.3 Chronic Dietary Aggregate Risks and DWLOCs

The results of the chronic aggregate risk assessment are presented below in Table 18. Chronic aggregate risks were not of concern for any subpopulation regardless of the source of drinking water, even considering the Florida surface water EECs. There is one chronic residential exposure scenario associated with the use of pet collars where the MOEs for children are of concern. As such, exposure from pet collars was not included in the chronic DWLOC calculations because of the risk concerns for this scenario and to illustrate chronic, aggregate risks for all others who are not exposed to collars.

Table 18: Chronic DWLOC Calculations							
Population Subgroup	cPAD (mg/kg/day)	Chronic Food Exposure (mg/kg/day)	Max. Chronic Water Exposure (mg/kg/day)	Chronic DWLOC (ug/L or ppb)	EECs		
					Surface Water (all PRZM/EXMS)		Ground Water (SciGrow) (ppb)
					FL Citrus (ppb)	OR Apples (ppb)	
All Commodities Using 1989 - 1992 CFSII Consumption Data							
General Population	0.010000	0.000032	0.009968	349	28	9	0.8
All Infants	0.010000	0.000054	0.009946	100	28	9	0.8
Children (1-6 yrs)	0.010000	0.000057	0.009943	99	28	9	0.8
Children (7-12 yrs)	0.010000	0.000036	0.009964	100	28	9	0.8
Females (13-50 yrs)	0.010000	0.000026	0.009974	299	28	9	0.8
Males (13-19 yrs)	0.010000	0.000022	0.009978	349	28	9	0.8
Males (20+ yrs)	0.010000	0.000031	0.009969	349	28	9	0.8
Seniors (55+ yrs)	0.010000	0.000031	0.009969	349	28	9	0.8
All Commodities Using 1994-1998 CFSII Consumption Data							
General Population	0.010000	0.000035	0.009965	349	28	9	0.8
All Infants	0.010000	0.000059	0.009941	99	28	9	0.8
Children (1-6 yrs)	0.010000	0.000074	0.009926	99	28	9	0.8
Children (7-12 yrs)	0.010000	0.000034	0.009966	100	28	9	0.8
Females (13-50 yrs)	0.010000	0.000028	0.009972	299	28	9	0.8
Males (13-19 yrs)	0.010000	0.000026	0.009974	349	28	9	0.8
Males (20+ yrs)	0.010000	0.000032	0.009968	349	28	9	0.8
Seniors (55+ yrs)	0.010000	0.000030	0.009970	349	28	9	0.8

5.4 Short-term Aggregate Risks and DWLOCs

The results of the short-term aggregate risk assessment are presented below in Table 19. The exposure scenarios which were considered in this assessment represent a broad range of carbaryl uses. The only scenarios for toddlers that were included were for the mosquito control and oyster bed uses. The Agency has risk concerns for all other scenarios that were addressed for toddlers based on residential exposures alone including uses on turf and uses on pets (see *Section 4.4.3.1: Residential Postapplication Exposure and Noncancer Risks*). In the residential assessment, youth (ages 10 to 12) were also considered in home garden scenarios. The risk estimates for these children are similar to that for adults so aggregate risks were calculated only for adults with the stipulation that the results represent both populations (i.e., risks are actually slightly worse for adults). For adults, the following postapplication exposures were considered: after mosquito control (doing heavy yardwork/lawncare); golfing; gardening (highest exposure activity - tree fruit harvest); and oyster harvesting. Adults doing heavy lawncare tasks after normal applications to turf were of concern for residential exposure alone so they were not considered in the aggregate assessment. Additionally, several aggregate assessments for homeowner handlers (most at average application rates) were completed based on application of dusts (gardens and pets): hose-end sprayer; liquid spray spot lawn treatments; and broadcast application of granulars to lawns. The handler scenarios are numbered and these correspond to the residential risk assessment scenario numbers. Risks for these handler scenarios at higher application rates (e.g., label maximums) were of concern for residential exposure alone so they were not considered in the aggregate assessment. All calculations for adults were completed for both women and men. Results were similar for both populations.

If surface water EECs based on Oregon apples or groundwater EECs from Sci-Grow are considered, aggregate risks are not of concern for the selected scenarios. If EECs from Florida citrus are considered, aggregate risks are not of concern for the selected scenarios except for application of dusts to gardens at the average rate keeping in mind that surface water is not a major drinking water source in Florida. [Note: Most DWLOCs exceed the corresponding EECs for groundwater by orders of magnitude. This should be considered along with the caution that it is possible that Sci-Grow might underestimate groundwater concentrations for carbaryl.]

Table 19: Short-term Aggregate Risk and DWLOC Calculations Using 1989-1992 CFSII Consumption Data

Population Subgroup	Target Agg. MOE	Food MOE	Nondietary Ing. MOE	Dermal MOE	Inhal. MOE	Aggregate MOE	Water MOE	Allowable Water Exposure (mg/kg/day)	DWLOC (ug/L or ppb)	EECs: Surface Water (all PRZM/EXMS) FL Citrus (ppb)	EECs: Surface Water (all PRZM/EXMS) OR Apples (ppb)	EECs: Ground Water (SciGrow) (ppb)
Postapplication Children												
Children (1-6 yrs) Aerial Mosquito Day 0	100	17544	562	2211	NA	437	130	0.007710	116	28	9	0.8
Children (1-6 yrs) Oyster Bed Day 0	100	17544	51681	68909	NA	11006	101	0.009909	149	28	9	0.8
Postapplication Adult Males												
Adult Male Aerial Mosquito Day 0-Lawncare	100	32258	NA	3700	NA	3319	103	0.009699	340	28	9	0.8
Adult Male Golfing Day 0-Max Rate	100	32258	NA	624	NA	612	120	0.008366	293	28	9	0.8
Adult Male Garden Day 0-High Expo.	100	32258	NA	579	NA	569	121	0.008242	289	28	9	0.8
Adult Male Oyster Bed Use Day 0, Swim	100	32258	301815	10856944	NA	29065	100	0.009966	349	28	9	0.8
Adult Male Consumer Product Handlers												
Adult Male Scen. #2 Garden Dust Avg Rate	100	32258	NA	120	1019	107	1580	0.000633	22	28	9	0.8
Adult Male Scen #3 Gard. Hose End, Avg Rate	100	32258	NA	158	134615	157	274	0.003648	128	28	9	0.8
Adult Male Scen #8 Lawn Spot-Liquids	100	32258	NA	509	17500	487	126	0.007948	278	28	9	0.8
Adult Male Scen #9 Dusting Dog Avg Rate	100	32258	NA	163	1077	141	343	0.002913	102	28	9	0.8
Adult Male/Scen # 12 Lawn Broadcast Granular	100	32258	NA	490	18315	470	127	0.007874	276	28	9	0.8
Postapplication Adult Females												
Adult Female Aerial Mosquito Day 0-Lawncare	100	38462	NA	3700	NA	3375	103	0.009704	291	28	9	0.8
Adult Female Golfing Day 0-Max Rate	100	38462	NA	624	NA	614	119	0.008371	251	28	9	0.8
Adult Female Garden Day 0-High Expo.	100	38462	NA	579	NA	570	121	0.008247	247	28	9	0.8
Adult Female Oyster Bed Use Day 0, Swim	100	38462	301815	10856944	NA	34007	100	0.009971	299	28	9	0.8
Adult Female Consumer Product Handlers												
Adult Female Scen. #2 Garden Dust Avg Rate	100	38462	NA	120	1019	107	1568	0.000638	19	28	9	0.8
Adult Female Scen #3 Gard. Hose End, Avg Rate	100	38462	NA	158	134615	158	274	0.003653	110	28	9	0.8
Adult Female Scen #8 Lawn Spot-Liquids	100	38462	NA	509	17500	488	126	0.007953	239	28	9	0.8
Adult Female Scen #9 Dusting Dog Avg Rate	100	38462	NA	163	1077	141	343	0.002918	88	28	9	0.8
Adult Female/Scen # 12 Lawn Broadcast Granular	100	38462	NA	490	18315	472	127	0.007879	236	28	9	0.8

5.5 Intermediate-term Aggregate Risks and DWLOCs

Separate intermediate-term aggregate risk and DWLOC calculations were not completed for carbaryl because the short-term aggregate risk estimates essentially present the same results since the hazard inputs are numerically identical. The only major differences would be the postapplication results where, instead of a single day exposure estimate, the exposures represent a 30 day average. The DWLOCs were not of concern for the short-term exposure scenarios and they would not be expected to be of concern for the intermediate-term scenarios since the exposures would be lowered because an average was used instead of a single day, higher exposure estimate.

5.6 Aggregate Cancer Risks and DWLOCs

The results of the aggregate cancer risk assessment are presented below in Table 20. The exposure scenarios which were considered in this assessment represent a broad range of carbaryl uses. The same scenarios for adults were considered as in the short-term assessment described above in *Section 5.4: Short-term Aggregate Risks and DWLOCs*. Aggregate cancer risks were not of concern for any subpopulation regardless of the source of drinking water, even considering the Florida surface water EECs.

Table 20: Aggregate Cancer Risk and DWLOC Calculations Using 1989-1992 CFSII Consumption Data

Population Subgroup	Q1* (mg/kg/day)	Negligible Risk Level	Target Maximum Exposure (mg/kg/day)	Chronic Food Exposure (mg/kg/day)	Residential Exposure LADD (mg/kg/day)	Aggregate Cancer Risk (Food & Residential)	Maximum Water Exposure (mg/kg/day)	DWLOC (ug/L or ppb)	EECs: Surface Water (all PRZM/EXMS) FL Citrus (ppb)	EECs: Surface Water (all PRZM/EXMS) OR Apples (ppb)	EECs: Ground Water (SciGrow) (ppb)
Postapplication Adult Males											
Adult Male/Aerial Mosquito Day 0-Lawncare	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00000067	2.77E-008	0.001111	39	28	9	0.8
Adult Male/Golfing Day 0-Max Rate	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00000400	3.06E-008	0.001108	39	28	9	0.8
Adult Male/Garden Day 0-High Expo.	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00000857	3.46E-008	0.001103	39	28	9	0.8
Adult Male/Oyster Bed Use Day 0, Swim	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00000001	2.71E-008	0.001112	39	28	9	0.8
Adult Male Consumer Product Handlers											
Adult Male/#2 Garden Dust Avg Rate	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00004343	6.51E-008	0.001068	37	28	9	0.8
Adult Male/#3 Garden Hose End, Avg Rate	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00003143	5.46E-008	0.001080	38	28	9	0.8
Adult Male/#8 Lawn Spot-Liquids	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00000987	3.58E-008	0.001102	39	28	9	0.8
Adult Male/#9 Dusting Dog Avg Rate	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00003223	5.53E-008	0.001080	38	28	9	0.8
Adult Male/#12 Lawn Broadcast Granular	8.75×10^{-4}	1.0×10^{-6}	0.001143	0.000031	0.00001025	3.61E-008	0.001102	39	28	9	0.8
Postapplication Adult Females											
Adult Female/Aerial Mosquito Day 0-Lawncare	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00000067	2.33E-008	0.001116	34	28	9	0.8
Adult Female/Golfing Day 0-Max Rate	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00000400	2.63E-008	0.001113	33	28	9	0.8
Adult Female/Garden Day 0-High Expo.	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00000857	3.03E-008	0.001108	33	28	9	0.8
Adult Female/Oyster Bed Use Day 0, Swim	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00000001	2.28E-008	0.001117	34	28	9	0.8
Adult Female Consumer Product Handlers											
Adult Female/#2 Garden Dust Avg Rate	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00004343	6.08E-008	0.001073	32	28	9	0.8
Adult Female/#3 Garden Hose End, Avg Rate	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00003143	5.03E-008	0.001085	33	28	9	0.8
Adult Female/#8 Lawn Spot-Liquids	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00000987	3.14E-008	0.001107	33	28	9	0.8
Adult Female/#9 Dusting Dog	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00003223	5.10E-008	0.001085	33	28	9	0.8
Adult Female/#12 Lawn Broadcast Granular	8.75×10^{-4}	1.0×10^{-6}	0.001143	2.6E-005	0.00001025	3.17E-008	0.001107	33	28	9	0.8

5.7 Summary of Aggregate Risks

In many residential scenarios, MOEs exceed the Agency's risk targets making the calculation of DWLOCs and aggregate risks for those scenarios inappropriate because exposure limits have already been exceeded. Additionally, acute dietary risks were also exceeded for infants and children (1 to 6 years old) at the 99.9th percentile when the Carbamate Market Basket Survey (CMBS) was not considered in the assessment. However, the risk picture could substantively change if residential risks are refined based on updated use information from the carbaryl use survey yet to be submitted to the Agency and the Agency regulates using the results of the CMBS. The Agency approach for calculating aggregate risks using different sources of data to create different exposure scenarios for illustrative purposes is consistent with Agency-wide guidance for exposure assessment and risk characterization (e.g., PDP and carbamate market basket survey, various water scenarios, and selected residential scenarios). The Agency takes this approach to allow for more informed risk management decisions that consider as much available data as possible along with the uncertainties associated with those data. For example, it is appropriate to present results based on both PDP and the carbamate market basket survey. PDP data are routinely used in Agency risk assessments and the market basket study is of sufficient quality for incorporation in the risk assessment. However, there are uncertainties associated with the use of each data source (e.g., rubbing of fruit prior to extraction in the carbamate market basket survey).

Keeping this in mind, the Agency completed DWLOC and aggregate risk calculations for illustrative purposes using a number of representative exposure scenarios where the residential and dietary risk estimates did not already exceed the Agency's level of concern. For example, an acute assessment with CMBS results included and short-term assessments where residential handler risks weren't already of concern were completed. The highest EECs for surface water were from Florida citrus but most drinking water in Florida is from groundwater. Therefore, results from surface water in Florida and the next highest values (Oregon apples) were considered in the assessment.

The acute aggregate assessment indicates that even with the use of the Carbamate Market Basket Survey (CMBS), aggregate risks when surface water is the source of drinking water, are still of concern for all infants, children (1 to 6 years old) and children (7 to 12 years old) regardless of whether or not Florida citrus or Oregon apple EECs are used (i.e., surface water is not a major drinking water source in Florida). If Florida citrus results are solely considered, aggregate risks are of concern for all subpopulations. Surface water EECs for Florida citrus exceed exposure limits, without even considering food intakes, for all populations. The surface water EECs for Oregon apples exceed exposure limits alone, without even considering food intakes, for infants and children. Acute aggregate risks for all subpopulations are not of concern if groundwater is the source of drinking water. Chronic aggregate risks were not of concern for any subpopulation regardless of the source of drinking water, even considering the Florida surface water EECs. In the short-term assessment, the Agency selected representative scenarios where residential risks alone were not of concern including mosquito control, oyster harvesting, golfing, garden harvest, and several handler scenarios (all at average rates, max rate scenarios were of concern for residential exposures alone). If surface water EECs based on Oregon apples or groundwater EECs from SciGrow are considered, aggregate risks are not of concern for the selected scenarios. If EECs from Florida citrus are considered, aggregate risks are not of concern for the selected scenarios except for application of dusts to gardens. Separate intermediate-term aggregate risk and DWLOC calculations were not completed for carbaryl because the short-term aggregate risk estimates essentially presented the same results since the hazard inputs were numerically identical. The only major differences would be the postapplication results where, instead of a single day exposure estimate, the exposures represented a 30 day average. Aggregate cancer risks were not of concern for any subpopulation regardless of the source of drinking water, even considering the Florida surface water EECs.

6.0 CUMULATIVE RISK

The Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall base its assessment of the risk posed by the chemical on, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

Carbaryl is a member of the carbamate class of pesticides. This class also includes the aldicarb, methomyl and oxamyl among others. HED did not perform a cumulative risk assessment as part of this reregistration review for carbaryl because HED has not yet initiated a review to determine if there are any other chemical substances that have a mechanism of toxicity common with that of carbaryl. For purposes of this reregistration decision, EPA has assumed that carbaryl does not have a common mechanism of toxicity with other substances.

The registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether carbaryl shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for carbaryl need to be modified or revoked. If HED identifies other substances that share a common mechanism of toxicity with carbaryl, HED will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment once the final guidance HED will use for conducting cumulative risk assessments is available.

HED has recently developed a framework that it proposes to use for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance reflects recent revisions based on review and comment from earlier guidance issued on June 30, 2000 (65 FR 40644-40650) that is available from the OPP Website at: http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-30/6049.pdf. The recently revised guidance is entitled *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have A Common Mechanism Of Toxicity* (January 14, 2002). In the guidance, it is stated that a cumulative risk assessment of substances that cause a common toxic effect by a common mechanism will not be conducted until an aggregate exposure assessment of each substance has been completed.

Before undertaking a cumulative risk assessment, HED will follow procedures for identifying chemicals that have a common mechanism of toxicity as set forth in the "*Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity*" (64 FR 5795-5796, February 5, 1999). HED will also address issues described in the document entitled

Consideration of the FQPA Safety Factor and Other Uncertainty Factors In Cumulative Risk Assessment of Chemicals Sharing a Common Mechanism of Toxicity (Draft: February 28, 2002).

7.0 OCCUPATIONAL RISK ASSESSMENT

This section of the risk assessment addresses exposures to individuals who are exposed as part of their employment. These exposures can occur because people have contact with carbaryl residues while using commercial products containing carbaryl (i.e., handlers) or by being in areas that have been previously treated (postapplication workers). A thorough understanding of how carbaryl is used is critical to the development of a quality risk assessment. Because this information is also critical to the dietary and residential exposure assessments presented above, available use information has already been summarized. Please refer to *Section 4.1: Summary of Registered Uses* for information on how carbaryl is used. All calculations for occupationally exposed people are based on this information. Also, for more detailed information pertaining to the occupational risk calculations, please refer to the Occupational and Residential Exposure Assessment (D281418) prepared by Jeff Dawson. The document D281418 contains detailed descriptions of the data used, methods, and risks calculated for each scenario.

Section 7.1: Occupational Handler Risk Assessment describes the data, methods, and risk results (both cancer and noncancer) associated with the use of commercial products which contain carbaryl. *Section 7.2: Occupational Postapplication Risk Assessment* describes the data, methods, and risk results associated with exposures to workers as they complete activities required for the production and maintenance of crops or other areas such as turf that might require the use of carbaryl. *Section 7.3: Occupational Risk Characterization* provides information pertaining to the quality of the assessment including data used, uncertainties with the methods, and any other information that might be used to describe the quality of the results. *Section 7.4: Human and Domestic Animal Incident Data Review* describes the analysis conducted by Agency epidemiologists.

7.1 Occupational Handler Risk Assessment

The Agency completes occupational handler risk assessments using scenarios as the basis for the calculations as described in the *U.S. EPA Guidelines For Exposure Assessment*. For commercial pesticide products, the Agency categorizes handler exposures based on the kinds of formulations (e.g., liquids or various solids), the kinds of equipment used to make applications (e.g., groundboom, aerial, or airblast), the nature of the task (e.g., mixing/loading, applying, or both combined), and the level of personal protection used. Identifying the duration of exposure is also a critical element in the development of a risk assessment to ensure that the proper hazard component is used.

For carbaryl uses, the Agency identified 28 major occupational exposure scenarios based on the types of equipment and techniques that potentially can be used for carbaryl applications. Most of the scenarios were classified as having short-term and intermediate-term exposures (up to 30 days and 30 days to several months, respectively). A few other scenarios have also been addressed that are thought to have long-term or chronic exposures (several months to every working day) associated with them in the greenhouse and floriculture industry.

The quantitative exposure/risk assessment developed for occupational handlers was based on the following scenarios. [Note: The numbers correspond to the tracking system included in D281418.]

Mixing/Loading
(1a) Dry Flowable for Aerial/Chemigation in Agriculture;
(1b) Dry Flowable for Airblast;
(1c) Dry Flowable for Groundboom;
(1d) Dry Flowable for High Pressure Handwand and Right of Way Sprayers;
(1e) Dry Flowable for LCO Applications;
(1f) Dry Flowable for Aerial Wide Area Uses;
(2a) Granular for Aerial;
(2b) Granular for Broadcast Spreader;
(3a) Liquids for Aerial/Chemigation;
(3b) Liquids for Airblast;
(3c) Liquids for Groundboom;
(3d) Liquids for High Pressure Handwand and Right of Way Sprayers;
(3e) Liquids for LCO Applications;
(3f) Liquids for Aerial Wide Area Uses;
(3g) Liquids for Ground Wide Area Uses;
(4a) Wettable Powder for Aerial/Chemigation;
(4b) Wettable Powder for Airblast;
(4c) Wettable Powder for Groundboom;
(4d) Wettable Powder for High Pressure Handwand and Right of Way Sprayers;
(4e) Wettable Powder for LCO Applications;
(4f) Wettable Powder for Aerial Wide Area Uses;

Applicator:
(5a) Aerial/Liquid Application;
(5b) Aerial/Liquid Wide Area Application;
(5c) Aerial/Granular Application;
(6a) Airblast Application;
(6b) Wide Area Ground Fogger (Airblast as surrogate);
(7) Groundboom Application;
(8) Solid Broadcast Spreader Application;
(9) Aerosol Can Application;
(10) Trigger Sprayer (RTU) Application;
(11) Right-of-Way Sprayer Application;
(12) High Pressure Handwand Application;
(13) Veterinary Technician/Animal Groomer Liquid Application;
(14) Veterinary Technician/Animal Groomer Dust Application;
(15) Granulars/Bait and Pellets Dispersed by Hand;
(16) Granulars/Bait and Pellets Dispersed with Spoon;

Mixer/Loader/Applicator:
(17) Low Pressure/High Volume Turfgun Application;
(18a) Wettable powder, Low pressure handwand;
(18b) Liquid: Low Pressure Handwand;
(19) Backpack;
(20) Granular Belly Grinder;
(21) Push-type Granular Spreader;
(22) Handheld Fogger;
(23) Powered Backpack;
(24) Granular Backpack;
(25) Tree Injection;
(26) Drenching/Dipping Seedlings For Propagation;
(27) Sprinkler Can;

Flaggers:
(28a) Flagging For Liquid Sprays; and
(28b) Flagging For Granular Applications.

For each of these scenarios, risk calculations were completed based on eight levels of personal protection that were defined based on different combinations of the following:

1) baseline protection (typical work clothing or a long-sleeved shirt and long pants, no respiratory protection and no chemical-resistant gloves);

2) minimum personal protective equipment (baseline scenario with the use of chemical-resistant gloves and a dust/mist respirator with a protection factor of 5);

3) maximum personal protective equipment (baseline scenario with the use of an additional layer of clothing (e.g., a pair of coveralls), chemical-resistant gloves, and an air purifying respirator with a protection factor of 10);

4) engineering controls (use of an appropriate engineering control such as a closed tractor cab or closed loading system for granulars or liquids).

Current labels mostly require single layer clothing, chemical-resistant gloves, and no respirator.

Data and Assumptions A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments, as described below. The assumptions and factors used in the risk calculations are consistent with current Agency policy for completing occupational exposure assessments (e.g., *PHED Surrogate Exposure Guide* and *Exposac Policy 9: Standard Values For Daily Acres Treated In Agriculture*). [Note: PHED is a database that contains monitored field data used for assessments. See *Section 4.4.2 Residential Handler Risk Assessment* above for further information.]

- Average body weight of an adult handler is 70 kg as described in the residential handler assessments (see Section 4.4.2).

- Several generic protection factors were used to calculate handler exposures. The protection factors used for clothing layers (i.e., 50%) and gloves (90%) have not been completely evaluated by the Agency. Additionally, protection factor was used to estimate exposures that involve engineering controls if required (98%). The values used for respiratory protection (i.e., PF 5 or PF 10) are based on the *NIOSH Respirator Decision Logic.*

- For cancer risk calculations, a value of 30 application events per year for all commercial applicator scenarios and 10 days per year to account for private growers was used. These values are supported by the data included in the University of California studies of seasonal labor in California and the recent Department of Labor National Agricultural Worker Survey (NAWS). The exposure duration values used by HED in the cancer risk assessment are consistent with those used for other chemicals (i.e., 35 working years and 70 year lifetime).

- In many scenarios, it is likely that a grower would mix, load, and apply chemicals all in one day because of limited labor, efficiency, or many other reasons. In most cases, mixing/loading and application are considered separate job functions because of the available data and also it allows for more flexibility in the risk management phase (e.g., assigning requirements for specific types of protective equipment).

- Flagging during aerial applications has been addressed even though it may be limited in nature (10 to 15% of aerial application operations). Engineering controls (e.g., Global Positioning Satellite technology) are now predominantly used by pilots as indicated by the 1998 National Agricultural Aviation Association (NAAA) survey of their membership.

- The maximum application rates allowed by labels were used in the risk assessments. If additional information, such as average or typical rates, were available, these values were used as well in order to allow risk managers to make a more informed risk management decision. Average application rates were available from the SMART meeting and BEAD’s QUA.

- The average occupational workday is assumed to be 8 hours. The daily areas to be treated were defined for each handler scenario (in appropriate units) by determining the amount that can be reasonably treated in a single day (e.g. acres, animals). The factors used for the carbaryl assessment are the same as those detailed in the HED Science Advisory Committee on Exposure *Policy 9: Standard Values for Daily Acres Treated in Agriculture*. The daily volumes handled and acres treated, excerpted from the policy, in each occupational scenario include:

- Aerial applications:1200 acres for large field crops and forest treatments, 350 acres for other field crops, and 7500 acres for mosquito control adulticide applications;
- Groundboom: 200 acres for large field crops (e.g., wheat and corn), 80 acres treated for other field crop groundboom applications, and 40 acres on golf course turf;
- Airblast: 40 acres treated for agricultural applications;
- 8 pet animals treated per day for veterinary and professional groomer uses[10];
- 1000 gallons of spray solution prepared when mixing/loading liquids for high pressure handwand application or making the application;
- 40 gallons when mixing/loading/applying liquids with a backpack sprayer or a low pressure handwand sprayer;
- 10 mounds per day treated for fire ant applications.[10]

- For direct pet animal treatments, the Residential SOPs, were used to define the amount of chemical that can be used to treat a single animal, which in turn was used to calculate total human dose levels. The actual per animal application rates used were ½ of a 6 oz bottle for liquid shampoos (0.5%) and ½ of 4 lb container for animal powders (10%).

- Ultra low volume applications for uses, such as adulticide mosquito control, were considered using a large acreage estimate to aerial applicators. The mosquito adulticide uses were evaluated in the same manner as other chemicals used for that purpose (e.g., the same acreage estimates were used as for other chemicals like fenthion and naled).

- There were several scenarios which were identified for which no appropriate exposure data are known to exist. These include: animal grooming dust application; dust applications in agriculture; handheld fogging for mosquito and other pest treatments; power backpack application; tree injection; and drenching/dipping seedlings (the mixing/loading component only of this scenario has been addressed quantitatively).

The unit exposure values (mg ai exposure/lb ai handled) used in this assessment were predominantly based on PHED and summarized in the surrogate exposure guidance. In addition to PHED, five studies were used by the Agency. One used carbaryl to quantify exposures for professional dog groomers. Two were completed by Aventis Crop Science using other chemicals that quantified exposures to granular products using a backpack application device. One was submitted by Bayer (now in the process of acquiring Aventis Crop Science and with a signed PHED data waiver) that quantified exposures using a ready-to-use trigger sprayer. Lastly, an ORETF (Outdoor Residential Exposure Task Force, of which Aventis Crop Science is a member) study that quantified exposures of professional

[10]The veterinary and fireant treatments are not included in the policy but represent values that have been used by HED in previous assessments.

lawncare operators using granular and liquid products. There are no data compensation issues with any of these data.[11] In all cases, what appears to be the best available data have been used to complete the calculations.

7.1.1 Occupational Handler Non-Cancer Risks

Noncancer risks were calculated using the MOE approach, as described under 4.4.2.1. The major differences are that personal protective devices are used and longer duration exposures (i.e., intermediate-term and chronic) have been considered as appropriate. Risk estimates for short- and intermediate-term exposures are similar because all numerical inputs for both durations and the target MOEs were identical. A NOAEL from the 21-day dermal toxicity study in rats using technical grade carbaryl was used to calculate results for both durations (i.e., 20 mg/kg/day). A NOAEL from the developmental neurotoxicity study in rats, that also observed at the same level in a subchronic neurotoxicity study in rats (i.e., 1 mg/kg/day), was used to calculate inhalation risks. The target MOE was 100 for all assessments. In the chronic assessments, a LOAEL (3.1. mg/kg/day) has been used from a 1 year dog feeding study for both dermal and inhalation exposures (with a dermal absorption factor of 12.7 percent applied). The target MOE for the chronic assessments is 300 because a LOAEL was used instead of a NOAEL.

Short-/Intermediate-term Risks: In most scenarios, MOEs meet or exceed the required uncertainty factor of 100 at some level of personal protection. For the most part, current label requirements for personal protection (single layer clothing, gloves, and no respirator) appear to be generally inadequate for most scenarios except for operations where exposures are low and the amount of chemical used is also low. Table 21 summarizes the results for short-term and intermediate-term occupational handlers. [Note: Scenarios where MOEs are still of concern (i.e., <100) for any personal protection considered are highlighted and just the minimum required personal protective equipment (PPE) is highlighted if it exceeds current label requirements but target MOEs can be achieved at higher than label requirements for mitigation.]

Table 21: Summary of Short-/Intermediate-Term Occupational Handler Noncancer Risks				
Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	Min. Req. PPE
Mixer/Loaders				
1a Dry Flowable: Aerial/Chemigation	1-2 (wheat/corn) 2-5 (veg., stone fruit, 24C on oysters)	1200 350	363-726 498-1244	**EC** **EC**
1b Dry Flowable: Airblast	7.5-16 (various fruit & nut trees) 5 (nuts) 1.1-3 (pome & stone fruit, grapes)	40 40 40	1360-2902 101 143-391	**EC** **SL/GL/PF5** Baseline

[11] Non-ORETF data included in MRIDs 451672-01 and 452507-01 were from studies submitted by Aventis Crop Science. The propoxur trigger sprayer study has a signed PHED data waiver but has not been included into PHED. It also is the property of Bayer Crop Science which has recently acquired Aventis Crop Science. Some of the handler exposure data used in this assessment are from the ORETF, of which Aventis Crop Science, is a member.

Table 21: Summary of Short-/Intermediate-Term Occupational Handler Noncancer Risks				
Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	Min. Req. PPE
1c Dry Flowable: Groundboom	1.5-2 (wheat/corn) 2 (strawberry/veg) 8 (turf/golf courses) 4 (turf/golf courses)	200 80 40 40	2177-2902 107 2721 108	**EC** Baseline **EC** Baseline
1d Dry Flowable: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	430	Baseline
1e Dry Flowable: Low press./High Vol. Turfgun	4 -8 (LCO on turf)	5	430-860	Baseline
1f Dry Flowable: Wide area aerial	2 (rangeland/forestry)	7500	**58**	**MOE < 100**
2a Granular: Aerial Application	2 (corn) 2 (corn)	1200 350	688 146	**EC** **SL/GL/PF5**
2b Granular: Solid broadcast spreader	1.5 (wheat/corn) 2 (wheat/corn) 2 (vegetables) 6 (turf/golf courses) 9 (turf/golf courses)	200 200 80 40 40	110 256 206 138 284	Baseline **SL/GL/PF5** Baseline Baseline **SL/GL/PF5**
3a Liquid: Aerial/Chemigation	1.5-2 (wheat, max corn) 1 (avg. corn) 5 (stone fruit) 2 (vegetables)	1200 1200 350 350	**57-76** 114 **78** 103	**All MOEs < 100** **EC** **MOE<100** **DL/GL/PF10**
3b Liquid: Airblast Application	16 (Citrus-24C in California) 7.5 (Citrus) 5 (Nuts) 1.1-3 (Grapes, pome & stone fruit)	40 40 40 40	100 168 149 248-677	**DL/GL/PF10** **SL/GL/PF5** SL/GL/NR SL/GL/NR
3c Liquid: Groundboom	1.5 (wheat) 2 (corn) 2 (strawberries) 8 (turf/golf courses) 4 (turf/golf courses)	200 200 80 40 40	168 126 186 157 186	**SL/GL/PF5** **SL/GL/PF5** SL/GL/NR **SL/GL/PF5** SL/GL/NR
3d Liquid: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	745	SL/GL/NR
3e Liquid: Low press./High Vol. Turfgun	4 -8 (LCO on turf)	5	745-1489	SL/GL/NR
3f Liquid: Wide area aerial	2 (Range/Forestry) 0.016 (Mosquito adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	7500 7500 7500 7500	**9** 248 121 **18**	**MOE < 100** SL/GL/NR **EC** **MOE < 100**
3g Liquid: Wide area ground	0.016 (Mosquito adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	3000 3000 3000	621 112 **45**	SL/GL/NR **SL/GL/PF5** **MOE < 100**
4a Wettable Powders: Aerial	1-2 (Wheat/corn) 5 (stone fruit) 2 (vegetables)	1200 350 350	**40-80** **55** 137	**All MOEs < 100** **MOE < 100** **EC**
4b Wettable Powders: Airblast	16 (Citrus-24C in California) 1.1-7.5 (Citrus, nuts, grapes, pome & stone fruit)	40 40	150 320-2180	**EC** **EC**

Table 21: Summary of Short-/Intermediate-Term Occupational Handler Noncancer Risks				
Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	Min. Req. PPE
4c Wettable Powders: Groundboom	1.5-2 (wheat/corn) 2 (strawberries) 4-8 (turf/golf courses)	200 80 40	240-320 599 299-599	**EC** **EC** **EC**
4d Wettable Powders: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	102	**SL/GL/PF5**
4e Wettable Powders: Low press./High Vol. Turfgun	4 (LCO on turf) 8 (LCO on turf)	5 5	102 205	**SL/GL/PF5** **SL/GL/PF5**
4f Wettable Powders: Wide area aerial	2 (Range/Forestry)	7500	**6**	**MOE<100**
Applicators				
5a Aerial: Agricultural uses, liquid sprays	1-1.5 (wheat/avg. corn) 2 (max corn) 5 (stone fruit) 2 (vegetables, 24C on oysters)	1200 1200 350 350	113-170 **85** 116 292	**EC** **MOE<100** **EC** **EC**
5b Aerial: Wide area uses, liquid sprays	2 (Range/Forestry) 0.016-0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	7500 7500 7500	**14** 181-1700 **27**	**MOE<100** **EC** **MOE<100**
5c Aerial: Agricultural uses, granular applications	2 (corn) 2 (corn)	1200 350	**21** **72**	**MOE<100** **MOE<100**
6a Airblast: Agricultural uses	16 (Citrus 24C in California) 2-7.5 (Citrus, nuts, grapes, pome & max. stone fruit) 1.1 (avg. stone fruit)	40 40 40	105 224-841 123	**EC** **EC** **SL/GL/PF5**
6b Airblast: Wide area uses, liquid sprays	0.016 (Mosquito adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	3000 3000 3000	113 150 **22**	**SL/GL/PF5** **EC** **MOE<100**
7 Groundboom	1.5-2 (Wheat, corn) 2 (Strawberries) 4-8 (Turf/golf course)	200 80 40	122-162 304 152-304	Baseline Baseline Baseline
8 Solid broadcast spreader (granular)	1.5-2 (Wheat, corn) 2 (Strawberries) 4-8 (Turf/golf course)	200 80 40	103-138 258 115-172	Baseline Baseline Baseline
9 Aerosol Can	0.01 lb ai/can	2 cans	324	Baseline
10 Trigger pump sprayer	0.01 lb ai/can	1 can	8772	SL/GL/NR
11 Right of way sprayer	1.5 lb ai/100 gallons	1000 gallons	199	SL/GL/NR
12 High pressure handwand	4 lb ai/100 gallons	1000 gallons	**66**	**MOE<100**
13 Animal groomer, liquid application	0.01 lb ai/dog	8 dogs	**9.7**	**MOE<100**
14 Animal groomer, dust application	0.2 lb ai/dog	8 dogs	8750	Baseline (dermal exp only)
15 Granulars & baits applied by hand	9 (Ornamentals & gardens)	1	**3.8**	**MOE<100**
16 Granulars & baits applied by spoon	9 (Ornamentals & garderns)	1	**75.1**	**MOE<100**

Table 21: Summary of Short-/Intermediate-Term Occupational Handler Noncancer Risks				
Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	Min. Req. PPE
Mixerr/Loader/Applicators				
17 Low pressure, high volume turfgun (ORETF Data)	8 (LCO Use on turf) 4 (LCO Use on turf)	5 5	**94** 104	**MOE<100** **SL/GL/PF5**
18a Wettable powder, low pressure handwand	1 lb ai/1000 ft^2 (poultry house) 2% solution (ornamentals)	20,000 ft^2 40 gallons	**8.3** 135	**MOE<100** **SL/GL/PF5**
18b Liquids, low pressure handwand	1 lb ai/1000 ft^2 (poultry house) 2% solution (ornamentals)	20,000 ft^2 40 gallons	127 1699	**SL/GL/PF5** SL/GL/NR
19 Backpack sprayer	1 lb ai/1000 ft^2 (poultry house) 2% solution (ornamentals)	20,000 ft^2 40 gallons	**42** 565	**MOE<100** Baseline
20 Granular, bellygrinder	9 (Turf)	1	**27**	**MOE<100**
21 Granular, push-type spreader	9 (Turf)	5	124	**SL/GL/PF5**
22 Handheld fogger	No data	No data	No data	No data
23 Power backpack	No data	No data	No data	No data
24 Granular, backpack	9 (Ornamentals)	1	1562	**DL/GL/NR**
25 Tree injection	No data	No data	No data	No data
26 Drench/dipping forestry/ornamentals	1.5 lb ai/100 gallons (Ornamental/seedling dip)	100 gallons	199	SL/GL/NR
27 Sprinkler can	2% solution (Ornamentals)	10 gallons	226	Baseline
Flaggers				
28a Flagger: liquid sprays	2 (Corn) 2 (Vegetables)	1200 350	249 111	**EC** Baseline
28b Flagger: granular applications	2 (Corn) 2 (Vegetables)	1200 350	101 345	Baseline Baseline

Baseline = Long pants, long-sleeved shirts, no gloves
SL = Single layer clothing with or without gloves (GL or NG)
DL = Double layer clothing (i.e., coveralls over SL) with or without gloves (GL or NG)
EC = Engineering controls
NR = No respirator
PF5 = Protection factor 5 respirator
PF10 = Protection factor 10 respirator
Current label = SL/GL/NR
Min. Req. PPE = level of PPE where MOEs > 100, where current label is exceeded or no adequate PPE is found, results are bold. MOEs which never exceed 100 are for highest feasible type of mitigation (e.g., engineering control in most cases).

Chronic Risks: MOEs were calculated for only a limited number of exposure ornamental use scenarios where the Agency believes that this kind of exposure pattern may exist. These calculations were also completed at different levels of personal protection as illustrated in Table 22. For most scenarios (3 of 5), MOEs meet or exceed the required uncertainty factor of 300 at some level of personal protection. The granular hand application scenarios are problematic. The uncertainty factor of 300 is required for the chronic exposure scenarios because a LOAEL and not a NOAEL was used for risk assessment.

Table 22: Summary of Chronic Occupational Handler Noncancer Risks

Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary	
			MOEs	Min. Req. PPE
Applicators				
15 Granulars & baits applied by hand	9 (Ornamentals & gardens)	1	**4.7**	**MOE<300**
16 Granulars & baits applied by spoon	9 (Ornamentals & garderns)	1	**92.6**	**MOE<300**
Mixer/Loader/Applicators				
18a Wettable powder, low pressure handwand	2% solution (ornamentals)	40 gallons	302	**DL/GL/PF10**
18b Liquids, low pressure handwand	2% solution (ornamentals)	40 gallons	3206	SL/GL/NR
19 Backpack sprayer	2% solution (ornamentals)	40 gallons	781	Baseline

Baseline = Long pants, long-sleeved shirts, no gloves
SL = Single layer clothing with or without gloves (GL or NG)
DL = Double layer clothing (i.e., coveralls over SL) with or without gloves (GL or NG)
EC = Engineering controls
NR = No respirator
PF5 = Protection factor 5 respirator
PF10 = Protection factor 10 respirator
Current label = SL/GL/NR
Min. Req. PPE = level of PPE where MOEs > 300, where current label is exceeded or no adequate PPE is found, results are bold. MOEs which never exceed 300 are for highest feasible type of mitigation (e.g., PPE in most cases).

7.1.2 Occupational Handler Cancer Risks

Cancer risks were calculated by multiplying the LADD to the Q_1* (8.75 x 10^{-4} (mg/kg/day)$^{-1}$), as described in 4.4.2.2. HED considered two distinct populations in the cancer risk assessment - private growers at 10 use events per year and commercial applicators with a use pattern of 30 days per year. The Agency has defined a range of acceptable cancer risks based on a policy memorandum dated August 14, 1996, by Office of Pesticide Programs Director Dan Barolo. This memo refers to a predetermined quantified "level of concern" for occupational carcinogenic risk. Risks that are 1 x 10^{-6} or lower require no risk management action. For those chemicals subject to reregistration, the Agency is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protection are warranted as is commonly applied with noncancer risk estimates (e.g., additional PPE or engineering controls). Carcinogenic risks that remain above 1×10^{-4} at the highest level of mitigation appropriate for that scenario remain a concern.

Cancer risks for private growers (i.e., 10 applications per year) were calculated for different exposure scenarios at different levels of personal protection. All scenarios for private growers have risks that are $<1x10^{-4}$ at some level of personal protection specified in the Barolo memo. In fact, for all but one scenario (Scen 4f: Mixing/loading Wettable Powders for wide area aerial applications) cancer risks are $<1x10^{-4}$ at current label requirements for personal protection. If a $1x10^{-6}$ risk level is specified as a concern, results are similar in that risks for a majority of scenarios are $<1x10^{-6}$ at current label requirements. In fact, only 8 of the 128 scenarios considered for private growers have cancer risks $>1x10^{-6}$ (and less than $1x10^{-4}$) even when the most protective ensembles of either protective clothing or engineering controls are considered. As with the risks calculated for private growers, cancer risks for commercial applicators (i.e., 30 applications per year) were calculated for different exposure scenarios at different levels of personal protection. Again, risks for all but one scenario (Scen 4f: Mixing/loading Wettable Powders for wide area aerial applications) are less than the $1x10^{-4}$ level specified in the Barolo memo at current label requirements for personal protection (i.e., risks for this scenario are $< 1x10^{-4}$ if additional protective clothing or equipment is used). If a $1x10^{-6}$ risk level is specified as a concern for commercial applicators, results indicate that risks for about half of the scenarios considered are $<1x10^{-6}$ at current label requirements and that only 21 of the 128 scenarios considered have cancer risks $>1x10^{-6}$ (and less than $1x10^{-4}$) even when the most protective ensembles of either protective clothing or engineering controls are considered. In general, the cancer risk estimates would lead to less restrictive measures when compared to the noncancer results. Table 23 below provides a summary of the cancer risks that have been calculated for private growers and commercial applicators.

Table 23: Summary of Occupational Handler Cancer Risks For Private Growers and Commercial Applicators

Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary			
			Private Growers		Commercial Applicators	
			Risk	Min. Req. PPE	Risk	Min. Req. PPE
Mixer/Loaders						
1a Dry Flowable: Aerial/Chemigation	1-2 (wheat/corn) 5 (stone fruit) 2 (vegetables, 24C on oysters)	1200 350 350	3.7 to $7.4x10^{-8}$ $5.4x10^{-8}$ $1.0x10^{-6}$	**EC** **EC** **SL/GL/PF10**	1.1 to $2.2x10^{-7}$ $1.6x10^{-7}$ $6.5x10^{-8}$	**EC** **EC** **EC**
1b Dry Flowable: Airblast	16 (Citrus, 24C in CA) 1.1-7.5 (grapes, various fruit & nut trees)	40 40	1.0x10-6 $6.9x10^{-8}$ to $4.7x10^{-7}$	Baseline Baseline	$5.9x10^{-8}$ 1.4 to $9.3x10^{-7}$	**EC** **DL/GL/PF10**
1c Dry Flowable: Groundboom	2 (corn) 1.5 (wheat) 2 (strawberry/veg) 8 (turf/golf courses) 4 (turf/golf courses)	200 200 80 40 40	$4.7x10^{-7}$ $6.3x10^{-7}$ $2.5x10^{-7}$ $5.0x10^{-7}$ $2.5x10^{-7}$	Baseline Baseline Baseline Baseline Baseline	$1.0x10^{-6}$ $3.7x10^{-8}$ $7.5x10^{-7}$ $1.0x10^{-6}$ $7.5x10^{-7}$	**DL/GL/NR** **EC** Baseline **DL/GL/PF5** Baseline
1d Dry Flowable: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	$6.3x10^{-8}$	Baseline	$1.9x10^{-7}$	Baseline
1e Dry Flowable: Low press./High Vol. Turfgun	4 -8 (LCO on turf)	5	3.1 to $6.3x10^{-8}$	Baseline	$9.4x10^{-8}$ to $1.9x10^{-7}$	Baseline
1f Dry Flowable: Wide area aerial	2 (rangeland/forestry)	7500	$4.6x10^{-7}$	**EC**	**$1.4x10^{-6}$**	**All < $1x10^{-6}$**

Table 23: Summary of Occupational Handler Cancer Risks For Private Growers and Commercial Applicators

Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary			
			Private Growers		Commercial Applicators	
			Risk	Min. Req. PPE	Risk	Min. Req. PPE
2a Granular: Aerial Application	2 (corn) 2 (corn)	1200 350	$5.0x10^{-7}$ $3.3x10^{-7}$	**SL/GL/PF5** Baseline	$9.5x10^{-7}$ $9.9x10^{-7}$	**DL/GL/PF5** Baseline
2b Granular: Solid broadcast spreader	1.5-2 (wheat/corn) 2 (vegetables) 6-9 (turf/golf courses)	200 80 40	1.4 to $1.9x10^{-7}$ $7.6x10^{-8}$ 1.1 to $1.7x10^{-7}$	Baseline Baseline Baseline	4.3 to $5.7x10^{-7}$ $2.3x10^{-7}$ 3.4 to $5.1x10^{-7}$	Baseline Baseline Baseline
3a Liquid: Aerial/Chemigation	1 (avg. corn) 1.5 (wheat) 2 (corn) 5 (stone fruit) 2 (vegetables)	1200 1200 1200 350 350	$9.7x10^{-7}$ $9.9x10^{-7}$ $8.5x10^{-7}$ $9.5x10^{-7}$ $4.9x10^{-7}$	**SL/GL/PF5** **DL/GL/PF5** SL/GL/NR **SL/GL/PF5** SL/GL/NR	**$1.1x10^{-6}$** **$1.4x10^{-6}$** $7.2x10^{-7}$ **$1.1x10^{-6}$** $8.6x10^{-7}$	**All < $1x10^{-6}$ All < $1x10^{-6}$** EC **All < $1x10^{-6}$** **DL/GL/PF5**
3b Liquid: Airblast Application	16 (citrus, 24C in CA) 1.1-7.5 (grapes, various fruit & nut trees)	40 40	$4.5x10^{-7}$ $3.1x10^{-8}$ to $2.1x10^{-7}$	SL/GL/NR SL/GL/NR	1.0x10-6 $9.3x10^{-8}$ to $6.4x10^{-7}$	**SL/GL/PF5** SL/GL/NR
3c Liquid: Groundboom	1.5-2 (wheat/corn) 2 (strawberries) 4-8 (turf/golf courses)	200 80 40	2.1 to $2.8x10^{-7}$ $1.1x10^{-7}$ 1.1 to $2.3x10^{-7}$	SL/GL/NR SL/GL/NR SL/GL/NR	6.4 to $8.5x10^{-7}$ $3.4x10^{-7}$ 3.4 to $6.8x10^{-7}$	SL/GL/NR SL/GL/NR SL/GL/NR
3d Liquid: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	$2.8x10^{-8}$	SL/GL/NR	$8.5x10^{-8}$	SL/GL/NR
3e Liquid: Low press./High Vol. Turfgun	4 -8 (LCO on turf)	5	1.4 to $2.8x10^{-8}$	SL/GL/NR	4.2 to $8.5x10^{-8}$	SL/GL/NR
3f Liquid: Wide area aerial	2 (Range/Forestry) 0.016 (Mosquito adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	7500 7500 7500 7500	**$3.0x10^{-6}$** $8.5x10^{-8}$ $7.9x10^{-7}$ **$1.5x10^{-6}$**	**All < $1x10^{-6}$** SL/GL/NR SL/GL/NR **All < $1x10^{-6}$**	**$9.1x10^{-6}$** $2.5x10^{-7}$ $6.8x10^{-7}$ **$4.5x10^{-6}$**	**All < $1x10^{-6}$** SL/GL/NR **EC** **All < $1x10^{-6}$**
3g Liquid: Wide area ground	0.016 (Mosquito Adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	3000 3000 3000	$3.4x10^{-8}$ $3.2x10^{-7}$ $6.0x10^{-7}$	SL/GL/NR SL/GL/NR **EC**	$1.0x10^{-7}$ $9.5x10^{-7}$ **$1.8x10^{-6}$**	SL/GL/NR SL/GL/NR **All < $1x10^{-6}$**
4a Wettable Powders: Aerial	1.5 (Wheat) 2 (Corn - max) 1 (Corn - typ) 5 (stone fruit) 2 (vegetables)	1200 1200 1200 350 350	$4.6x10^{-7}$ $6.1x10^{-7}$ $3.1x10^{-7}$ $4.4x10^{-7}$ $1.8x10^{-7}$	**EC** **EC** **EC** **EC** **EC**	**$1.4x10^{-6}$** **$1.8x10^{-6}$** $9.2x10^{-7}$ **$1.3x10^{-6}$** $5.3x10^{-7}$	**All < $1x10^{-6}$** **All < $1x10^{-6}$** **EC** **All < $1x10^{-6}$** **EC**
4b Wettable Powders: Airblast	16 (Citrus-24C in California) 7.5 (Citrus) 5 (Nuts) 3 (Pome & stone fruit) 2 (Grapes) 1.1(Avg. stone fruit)	40 40 40 40 40 40	$1.6x10^{-7}$ $7.6x10^{-8}$ $1.0x10^{-6}$ $6.2x10^{-7}$ $8.8x10^{-7}$ $4.9x10^{-7}$	**EC** **EC** **SL/GL/PF5** **SL/GL/PF5** SL/GL/NR SL/GL/NR	$4.9x10^{-7}$ $2.3x10^{-7}$ $1.5x10^{-7}$ $9.2x10^{-8}$ $1.0x10^{-6}$ $5.7x10^{-7}$	**EC** **EC** **EC** **EC** **DL/GL/PF5** **DL/GL/PF5**
4c Wettable Powders: Groundboom	1.5 (wheat) 2 (corn) 2 (strawberries) 8 (turf/golf courses) 4 (turf/golf courses)	200 200 80 40 40	$7.6x10^{-8}$ $1.0x10^{-7}$ $8.3x10^{-7}$ $8.1x10^{-8}$ $8.3x10^{-7}$	**EC** **EC** **SL/GL/PF5** **EC** **SL/GL/PF5**	$2.3x10^{-7}$ $3.1x10^{-7}$ $1.2x10^{-7}$ $2.4x10^{-7}$ $1.2x10^{-7}$	**EC** **EC** **EC** **EC** **EC**
4d Wettable Powders: High Press HW/ROW Sprayer	4 lb ai/100 gal (poultry)	1000 gal	$4.4x10^{-7}$	SL/GL/NR	$5.2x10^{-7}$	**DL/GL/PF5**
4e Wettable Powders: Low press./High Vol. Turfgun	4 (LCO on turf) 8 (LCO on turf)	5 5	$2.2x10^{-7}$ $4.4x10^{-7}$	SL/GL/NR SL/GL/NR	$6.6x10^{-7}$ $6.2x10^{-7}$	SL/GL/NR **SL/GL/PF5**
4f Wettable Powders: Wide area aerial	2 (Range/Forestry)	7500	**$3.8x10^{-6}$**	**All < $1x10^{-6}$**	**$1.1x10^{-5}$**	**All < $1x10^{-6}$**

Table 23: Summary of Occupational Handler Cancer Risks For Private Growers and Commercial Applicators						
Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary			
			Private Growers		Commercial Applicators	
			Risk	Min. Req. PPE	Risk	Min. Req. PPE
Applicators						
5a Aerial: Agricultural uses, liquid sprays	1-2 (wheat/corn) 5 (stone fruit) 2 (vegetables, 24C on oysters)	1200 350 350	1.6 to 3.2x10^{-7} 2.3x10^{-7} 9.2x10^{-8}	**EC** **EC** **EC**	4.7 to 9.5x10^{-7} 6.9x10^{-7} 2.8x10^{-7}	**EC** **EC** **EC**
5b Aerial: Wide area uses, liquid sprays	2 (Range/Forestry) 0.016 (Mosquito adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	7500 7500 7500 7500	**2.0x10^{-6}** 1.6x10^{-8} 1.5x10^{-7} 9.8x10^{-7}	**All < 1x10^{-6}** **EC** **EC** **EC**	**5.9x10^{-6}** 4.7x10^{-8} 4.4x10^{-7} **3.0x10^{-6}**	**All < 1x10^{-6}** **EC** **EC** **All < 1x10^{-6}**
5c Aerial: Agricultural uses, granular applications	2 (corn) 2 (corn)	1200 350	6.2x10^{-7} 1.8x10^{-7}	**EC** **EC**	**1.9x10^{-6}** 5.5x10^{-7}	**All < 1x10^{-6}** **EC**
6a Airblast: Agricultural uses	16 (Citrus 24C in California) 7.5 (Citrus) 5 (Nuts) 3 (Pome & stone fruit) 2 (Grapes) 1.1 (Avg pome & stone fruit)	40 40 40 40 40 40	2.7x10^{-7} 1.3x10^{-7} 9.9x10^{-7} 1.0x10^{-6} 6.9x10^{-7} 3.8x10^{-7}	**EC** **EC** **DL/GL/PF5** Baseline Baseline Baseline	8.2x10^{-7} 3.9x10^{-7} 2.6x10^{-7} 1.5x10^{-7} 1.0x10^{-7} 7.9x10^{-7}	**EC** **EC** **EC** **EC** **EC** SL/GL/NR
6b Airblast: Wide area fogger	0.016 (Mosquito adulticide) 0.15 (Mosquito adulticide) 1 (Mosquito adulticide)	3000 3000 3000	4.1x10^{-7} 1.9x10^{-7} **1.3x10^{-6}**	Baseline **EC** **All < 1x10^{-6}**	8.6x10^{-7} 5.8x10^{-7} **3.9x10^{-6}**	SL/GL/NR **EC** **All < 1x10^{-6}**
7 Groundboom	1.5-2 (Wheat/corn) 2 (Strawberries) 8 (Turf/golf course) 4 (Turf/golf course)	200 80 40 40	1.3 to 1.7x10^{-7} 6.9x10^{-8} 1.4x10^{-7} 6.9x10^{-8}	Baseline Baseline Baseline Baseline	3.9 to 5.2x10^{-7} 2.1x10^{-7} 4.1x10^{-7} 2.1x10^{-7}	Baseline Baseline Baseline Baseline
8 Solid broadcast spreader (granular)	1.5-2 (Wheat/corn) 2 (Strawberries) 4-8 (Turf/golf course)	200 80 40	1.3 to 1.7x10^{-7} 6.7x10^{-8} 1.0 to 1.5x10^{-7}	Baseline Baseline Baseline	3.8 to 5.0x10^{-7} 2.0x10^{-7} 3.0 to 4.5x10^{-7}	Baseline Baseline Baseline
9 Aerosol Can	0.01 lb ai/can	2 cans	8.7x10^{-8}	Baseline	2.6x10^{-7}	Baseline
10 Trigger pump sprayer	0.01 lb ai/can	1 can	3.1x10^{-9}	SL/GL/NR	9.4x10^{-9}	SL/GL/NR
11 Right of way sprayer	1.5 lb ai/100 gallons	1000 gallons	4.3x10^{-7}	Baseline	4.1x10^{-7}	SL/GL/NR
12 High pressure handwand	4 lb ai/100 gallons	1000 gallons	6.6x10^{-7}	**SL/GL/PF5**	1.1x10^{-6}	**All < 1x10^{-6}**
13 Animal groomer, liquid application	0.01 lb ai/dog	8 dogs	**3.1x10^{-6}**	**All < 1x10^{-6}**	**9.4x10^{-6}**	**All < 1x10^{-6}**
14 Animal groomer, dust application	0.2 lb ai/dog	8 dogs	3.5x10^{-9}	Baseline	1.0x10^{-8}	Baseline
15 Granulars & baits applied by hand	9 (Ornamentals & gardens)	1	**8.0x10^{-6}**	**All < 1x10^{-6}**	**2.4x10^{-5}**	**All < 1x10^{-6}**
16 Granulars & baits applied by spoon	9 (Ornamentals & garderns)	1	4.6x10^{-7}	SL/GL/NR	**1.2x10^{-6}**	**All < 1x10^{-6}**
Mixerr/Loader/Applicators						
17 Low pressure, high volume turfgun (ORETF Data)	8 (LCO Use on turf) 4 (LCO Use on turf)	5 5	3.1x10^{-7} 6.1x10^{-7}	SL/GL/NR SL/GL/NR	9.7x10^{-7} 9.2x10^{-7}	**DL/GL/PF5** SL/GL/NR
18a Wettable powder, low pressure handwand	1 lb ai/1000 ft^2 (poultry house) 2% solution (ornamentals)	20,000 ft^2 40 gallons	**3.1x10^{-6}** 3.0x10^{-7}	**All < 1x10^{-6}** SL/GL/NR	**9.2x10^{-6}** 9.0x10^{-7}	**All < 1x10^{-6}** SL/GL/NR

Table 23: Summary of Occupational Handler Cancer Risks For Private Growers and Commercial Applicators						
Scenario	Rate (lb ai/acre) [unless noted]	Area Treated (acres/day) [unless noted]	Risk Summary			
			Private Growers		Commercial Applicators	
			Risk	Min. Req. PPE	Risk	Min. Req. PPE
18b Liquids, low pressure handwand	1 lb ai/1000 ft^2 (poultry house) 2% solution (ornamentals)	20,000 ft^2 40 gallons	$2.1x10^{-7}$ $1.2x10^{-8}$	**SL/GL/PF5** SL/GL/NR	$6.2x10^{-7}$ $3.5x10^{-8}$	**SL/GL/PF5** SL/GL/NR
19 Backpack sprayer	1 lb ai/1000 ft^2 (poultry house) 2% solution (ornamentals)	20,000 ft^2 40 gallons	$7.0x10^{-7}$ $4.8x10^{-8}$	**DL/GL/PF5** Baseline	**$2.2x10^{-6}$** $1.4x10^{-7}$	**All < $1x10^{-6}$** Baseline
20 Granular, bellygrinder	9 (Turf)	1	**$1.1x10^{-6}$**	**All < $1x10^{-6}$**	**$3.4x10^{-6}$**	**All < $1x10^{-6}$**
21 Granular, push-type spreader	9 (Turf)	5	$4.0x10^{-7}$	Baseline	$8.2x10^{-7}$	SL/GL/NR
22 Handheld fogger	No data	No data	No data	No data	No data	No data
23 Power backpack	No data	No data	No data	No data	No data	No data
24 Granular, backpack	9 (Ornamentals)	1	$1.9x10^{-8}$	**DL/GL/NR**	$5.8x10^{-8}$	**DL/GL/NR**
25 Tree injection	No data	No data	No data	No data	No data	No data
26 Drench/dipping forestry/ornamentals	1.5 lb ai/100 gallons (Ornamental/seedling dip)	100 gallons	$1.1x10^{-7}$	SL/GL/NR	$3.2x10^{-7}$	SL/GL/NR
27 Sprinkler can	2% solution (Ornamentals)	10 gallons	$1.3x10^{-7}$	Baseline	$4.0x10^{-7}$	Baseline
Flaggers						
28a Flagger: liquid sprays	2 (Corn) 2 (Vegetables)	1200 350	$7.2x10^{-7}$ $2.1x10^{-7}$	Baseline Baseline	$3.5x10^{-7}$ $6.3x10^{-7}$	**EC** Baseline
28b Flagger: granular applications	2 (Corn) 2 (Vegetables)	1200 350	$2.1x10^{-7}$ $6.1x10^{-8}$	Baseline Baseline	$6.2x10^{-7}$ $1.8x10^{-7}$	Baseline Baseline

Baseline = Long pants, long-sleeved shirts, no gloves
SL = Single layer clothing with or without gloves (GL or NG)
DL = Double layer clothing (i.e., coveralls over SL) with or without gloves (GL or NG)
EC = Engineering controls
NR = No respirator
PF5 = Protection factor 5 respirator
PF10 = Protection factor 10 respirator
Current label = SL/GL/NR
Min. Req. PPE = level of PPE where cancer risks > $1x10^{-6}$, where current label is exceeded or no adequate PPE is found, results are bold. Risks which never exceed $1x10^{-6}$ are for highest feasible type of mitigation (e.g., engineering control in most cases).

7.2 Postapplication Exposures and Risks

Workers can be exposed to carbaryl residues by entering previously treated areas to perform activities. Exposure varies with the specific tasks (i.e., transfer coefficient), the level of carbaryl residue in the environment (i.e., DFR or TTR depending upon crop), and the duration of the activity. Calculations were completed using the same approaches as already outlined above for the residential postapplication risk assessments (*Section 4.4.3: Residential Postapplication Risks*).

An administrative approach, the Restricted Entry Interval (REI), is used by the Agency to manage risks for postapplication workers doing hand labor activities that require direct contact with treated plants. The REI is the amount of time required between application of a pesticide and engaging in a task or activity in a treated field that it takes for residues to dissipate to an appropriate level. Current labels for carbaryl specify REIs of 12 hours after application for all crop/cultural practice combinations. In other cases (e.g., use of a combine or other mechanical harvesting) such as those specified in the Agency's Worker Protection Standard (40CFR170) where no contact will occur, the Agency does not rely on the REI approach but adheres to the guidance included in §170.110.(c)(3) that allows for entry if the criteria are met. The Agency also considers short-term excursions for people for such activities as unclogging machinery as stipulated in the guidance included in §170.112.(c). The Agency encourages the use of viable engineering controls and other means to reduce exposures provided they are not overly burdensome for actual workers. Generally, it should also be noted that the use of personal protective equipment or other types of equipment to reduce exposures for postapplication workers is not considered a viable alternative for the regulatory process except in specialized situations (e.g., a rice scout will wear rubber boots in flooded paddies).

As with the occupational handlers, a scenario-driven approach is used to assess risks for reentry workers. The Agency's *Policy 003.1 Science Advisory Council For Exposure Policy Regarding Agricultural Transfer Coefficients* is used to define the scenarios. This policy presents various transfer coefficients which represent the range of activities associated with 18 distinct crop/agronomic groupings based on different types of job tasks or activities needed to produce fruits, vegetables, grains, and other crops. In this scheme, carbaryl uses were identified in all of the crop groupings included in the policy. As such, all agronomic crop group/transfer coefficients included in this policy were used to calculate postapplication risks for carbaryl.

- Low Berry (e.g., lowbush blueberries, cranberries, strawberries);
- Bunch/bundle (e.g., bananas, hops, tobacco);
- Field/row crops, low/medium (e.g., alfalfa, barley, beans, cotton, peanuts, peas);
- Field/row crops, tall (e.g., corn, sorghum, sunflowers);
- Cut flowers (e.g., floriculture crops);
- Sugarcane;
- Trees/fruit, deciduous (e.g., apples, apricots, cherry, peaches, pears);
- Trees/fruit, evergreen (e.g., avocados, Christmas trees, citrus);
- Trees/nut (e.g., almonds, hazelnuts, macadamia, pecans, walnuts);
- Turf/sod (e.g., golf courses, sod farms);
- Vegetable/root (e.g., beets, carrots, onions, potatoes, turnips);
- Vegetable/cucurbit (e.g., cantelope, cucumber, squash, watermelon);
- Vegetable/fruiting (e.g., eggplant, pepper, tomato, okra);
- Vegetable/head and stem brassica (e.g., broccoli, cauliflower, brussel sprouts, cauliflower);
- Vegetables/leafy (e.g., collards, greens, lettuce, parsley, spinach, napa);
- Vegetables/stem and stalk (e.g., artichoke, asparagus, pineapple);
- Vine/trellis (e.g., blackberries, blueberries, grapes, kiwi, raspberries); and
- Nursery crops (e.g., container and B&B ornamentals).

[Note: This assessment includes the latest transfer coefficients for nursery crops which have been recently submitted by ARTF and reviewed by the Agency. Additionally, the transfer coefficient for fruit tree hand thinning has been reduced from original policy estimates based on a reinterpretation by the Agency of the dataset upon which it was based.]

Data and Assumptions A series of assumptions and exposure factors served as the basis for completing the occupational postapplication risk assessments, as described below. The assumptions and factors used in the risk calculations are consistent with current Agency policy for completing occupational exposure assessments (e.g., *Exposac Policy 3* and guidelines for handling DFR data). The assumptions and factors used in the risk calculations include:

- Many assumptions and factors which are common to both handler and postapplication risk assessments are detailed in *Section 7.1: Occupational Handler Risk Assessment* (e.g., body weight). One major difference is that in the handler assessment, many different combinations of application rates and crop acres treated were considered but in the postapplication assessment, generally only maximum application rates were considered.

- Four dislodgeable foliar residue (DFR) studies were submitted that meet current Agency guidelines for sampling techniques and data quality. These studies were conducted with carbaryl by the Agricultural Re-entry Task Force (ARTF) using Iwata's DFR sampling method on tobacco (harvesting), olives (pruning), sunflowers (scouting), and cabbage (weeding). [Note: Aventis Crop Science is a member of the ARTF so there are no data compensation issues associated with the use of these data.] The percent of transferability averaged approximately 16 percent of the application rate for the crops. A turf transferrable residue (TTR) study was also completed by Aventis Crop Science using the ORETF roller method. The percent of transferability averaged approximately 1.1 percent for turf measurements at three different sites. HED used the values from these five studies for all postapplication crops and scenarios as the transferability is in the appropriate range for use in risk assessments.

- Short-term noncancer risks were calculated by comparing single day exposures based on the dissipation of carbaryl residues (i.e., single day risks were calculated based on daily DFR dissipation values over time). With the intermediate-term postapplication risk calculations, 30-day averages based on DFR dissipation and an appropriate duration for the endpoint were used to calculate postapplication risks. In the long-term assessment, a 30 day average was used based on the likelihood that carbaryl could be sprayed at least once a month in the ornamental industry. The endpoints used are the same as those described above for the dermal component in the handler assessments (i.e., NOAEL of 20 mg/kg/day from 21-day dermal rat toxicity study using technical material - target MOE = 100 and LOAEL of 3.1 mg/kg/day from a chronic dog feeding study with a dermal absorption factor defined in rats - target MOE = 300).

- A standard pseudo-first order kinetics analysis was used to analyze carbaryl residue dissipation over time as outlined in the Agency's draft *Series 875 Postapplication Exposure Monitoring Guidelines*. A more sophisticated curve-fitting approach was not warranted because the correlation coefficients in the analysis were appropriate and the data have been used generically to extrapolate to a variety of other crops where decay rates and mechanisms may differ.

- When the available DFR data were extrapolated to other crops, the data were adjusted for differences in application rate using a simple proportional approach. Carbaryl-specific residue dissipation data were extrapolated to crops where no data were available. The tobacco DFR data were used to complete all assessments for the crop/activity combinations included in the bunch/bundle, sugarcane, and vine/trellis agronomic crop groups. The olive DFR data were used to complete all assessments for the crop/activity combinations included in all of the tree fruit and nut crop groups. The sunflower DFR data were used to complete all assessments for the crop/activity combinations in the tall field/row crop group. No extrapolation was required in this assessment. The cabbage study was based on groundboom application, which is thought to be much more prevalent in the overall use pattern for carbaryl. The cabbage DFR data were used to complete all assessments for the crop/activity combinations included in the berry, cut flower, low/medium field and row, and all vegetable (i.e., stem/stalk, brassica, leafy, fruiting, cucurbits, root) agronomic crop groups. The turf TTR data were used to complete all assessments for the crop/activity combinations for the turf agronomic crop group. No extrapolation was required in this assessment.

- There were several scenarios for which no appropriate exposure data are known to exist. There are many kinds of potential exposure pathways that do not involve foliar contact that have not been addressed in this risk assessment. The scenarios include: transplanting many crops including in the ornamental and forestry industry; thinning some crops such as hops; some partially mechanized operations that also involve human contact (e.g., cotton harvesting where module builders and trampers are used); various operations with Christmas trees such as pruning or baling; and various operations with nut production such as sweeping for harvest.

- Aventis Crop Science is in the process of conducting a biomonitoring study with postapplication workers on key crops of concern (i.e., apples and cherries). The activities that were monitored included hand thinning of apples and hand harvest of both apples and cherries. Based on discussions with Aventis Crop Science, the preliminary results indicate that levels are similar to those predicted in the Agency's occupational postapplication risk assessment.

7.2.1 Occupational Postapplication Noncancer Risks

Current label requirements specify 12 hour REIs. For all but the lowest exposure scenarios in some crops, short-term MOEs are of concern (i.e., less than the required uncertainty factor of 100) at the current REI. Generally, short-term MOEs meet or exceed the Agency uncertainty factor in the range of 3 to 5 days for lower to medium exposure activities and from 8 to 12 days after application in most higher exposure scenarios. Intermediate-term MOEs are not of concern generally for low to medium level exposures but are of concern for higher level exposures such as harvesting in some crops. Chronic exposures are of concern for the cut flower industry but not for general greenhouse and nursery production activities. Table 24 below provides a summary of the noncancer risks that have been calculated for each crop group and each duration of exposure. The information presented includes the short-term MOEs on the day of application, the day after application where the short-term MOEs meet or exceed the target of 100, the intermediate-term MOEs based on 30 day average exposures, and chronic MOEs also based on 30 day average exposures (only for a limited number of scenarios).

Table 24: Summary of Carbaryl Noncancer Postapplication Worker Risks

Crop Group	Result Type	Exposure Descriptor				
		Very Low	Low	Medium	High	Very High
Low Berry	ST MOE Day 0	NA	184	NA	49	NA
	Days For ST MOE > UF	NA	0	NA	4	NA

Table 24: Summary of Carbaryl Noncancer Postapplication Worker Risks						
Crop Group	Result Type	Exposure Descriptor				
		Very Low	Low	Medium	High	Very High
	IT 30 Day Avg MOE	NA	991	NA	264	NA
Bunch/Bundle	ST MOE Day 0	NA	411	32	21	NA
	Days For ST MOE > UF	NA	0	6	8	NA
	IT 30 Day Avg MOE	NA	2365	182	118	NA
Low /Med. Field/Row Crops	ST MOE Day 0	NA	982	65	39	NA
	Days For ST MOE > UF	NA	0	3	5	NA
	IT 30 Day Avg MOE	NA	5286	352	211	NA
Tall Field/Row Crops	ST MOE Day 0	NA	245	61	25	<1
	Days For ST MOE > UF	NA	0	4	11	+30
	IT 30 Day Avg MOE	NA	970	242	97	6
Cut Flowers	ST MOE Day 0	NA	30	18	11	NA
	Days For ST MOE > UF	NA	7	9	12	NA
	IT 30 Day Avg MOE	NA	159	99	57	NA
	Chronic MOE	NA	194	121	69	NA
Sugarcane	ST MOE Day 0	NA	NA	55	27	NA
	Days For ST MOE > UF	NA	NA	3	7	NA
	IT 30 Day Avg MOE	NA	NA	315	158	NA
Decid. Fruit Trees	ST MOE Day 0	1455	146	NA	49	NA
	Days For ST MOE > UF	0	0	NA	8	NA
	IT 30 Day Avg MOE	4450	445	NA	148	NA
Evergreen Fruit Trees	ST MOE Day 0	582	58	19	NA	NA
	Days For ST MOE > UF	0	6	17	NA	NA
	IT 30 Day Avg MOE	1780	178	59	NA	NA
Nut Trees	ST MOE Day 0	NA	175	NA	35	NA
	Days For ST MOE > UF	NA	0	NA	11	NA
	IT 30 Day Avg MOE	NA	534	NA	107	NA

Table 24: Summary of Carbaryl Noncancer Postapplication Worker Risks						
Crop Group	Result Type	Exposure Descriptor				
		Very Low	Low	Medium	High	Very High
Turf/Sod	ST MOE Day 0	NA	312	NA	10	NA
	Days For ST MOE > UF	NA	0	NA	14	NA
	IT 30 Day Avg MOE	NA	1505	NA	46	NA
Root Veg.	ST MOE Day 0	NA	245	49	29	NA
	Days For ST MOE > UF	NA	0	4	7	NA
	IT 30 Day Avg MOE	NA	1322	264	159	NA
Cucurbit Veg.	ST MOE Day 0	NA	147	49	29	NA
	Days For ST MOE > UF	NA	0	4	7	NA
	IT 30 Day Avg MOE	NA	793	264	159	NA
Fruiting Veg.	ST MOE Day 0	NA	147	105	74	NA
	Days For ST MOE > UF	NA	0	0	2	NA
	IT 30 Day Avg MOE	NA	793	566	396	NA
Brassica	ST MOE Day 0	NA	37	18	15	NA
	Days For ST MOE > UF	NA	6	9	11	NA
	IT 30 Day Avg MOE	NA	198	99	79	NA
Leafy Veg.	ST MOE Day 0	NA	147	49	29	NA
	Days For ST MOE > UF	NA	0	4	7	NA
	IT 30 Day Avg MOE	NA	793	264	159	NA
Stem/stalk Veg.	ST MOE Day 0	NA	137	82	41	NA
	Days For ST MOE > UF	NA	0	1	5	NA
	IT 30 Day Avg MOE	NA	788	473	236	NA
Vine/trellis	ST MOE Day 0	NA	147	74	15	7
	Days For ST MOE > UF	NA	0	2	11	14
	IT 30 Day Avg MOE	NA	793	396	79	40
Nursery/ Ornamentals	ST MOE Day 0	NA	669	421	184	NA
	Days For ST MOE > UF	NA	0	0	0	NA
	IT 30 Day Avg MOE	NA	3604	2266	991	NA
	Chronic MOE	NA	4399	2765	1210	NA

7.2.2 Occupational Postapplication Exposure and Risk Estimates for Cancer

Cancer risks for private growers (i.e., 10 exposures/year) and commercial farmworkers (i.e., 30 exposures/year) were calculated for different crop groups as described above and summarized in Table 25 below. Current label requirements specify 12 hour REIs. For all scenarios, cancer risks are $<1x10^{-4}$ on the day of application (i.e., at the current REI). Likewise, cancer risks are $<1x10^{-6}$ on the day of application for most crop/activity scenarios with private growers and also for low to medium exposures for commercial farmworkers. In fact, risks for all scenarios were in the 10^{-6} range in all but two scenarios for commercial farmworkers participating in very high exposure activities (e.g., sweetcorn handharvesting) on the day of application. In these three cases, risks were in the 10^{-5} range on the day of application. For private growers, it takes approximately 5 days for risks to decline to $<1x10^{-6}$ for crop/activity combinations that exceed $1x10^{-6}$ on the day of application. For commercial farmworkers, it takes approximately 8 days for risks to reach the target level of concern of $<1x10^{-6}$. The 1996 Barolo memo which focused on cancer risk management should be considered in the interpretation of these results. Current label requirements appear to be adequate for all postapplication cancer risks if the 10^{-4} range is used for risk management. If the 10^{-6} risk range is considered, it also appears that the current REI appears adequate to address cancer risks for many crop/activity combinations. However, for higher exposure situations, longer duration REIs are predicted. In all cases, REIs predicted based on cancer risks are less restrictive or similar (i.e., within a day or two for commercial farmworkers) than those predicted based on the noncancer effects of carbaryl. In no cases do cancer risks indicate more restrictive REIs than for noncancer risks calculated for the corresponding crop/activity exposure scenario.

Table 25: Summary of Carbaryl Cancer Postapplication Worker Risks						
Crop Group	Result Type	Exposure Descriptor (From Policy 003)				
		Very Low	Low	Medium	High	Very High
Low Berry	Private Grower Day 0 Risk	NA	1.7×10^{-7}	NA	6.2×10^{-7}	NA
	Private Grower Days < $1x10^{-6}$	NA	0	NA	0	NA
	Com.. Farmworker Day 0 Risk	NA	5.0×10^{-7}	NA	1.9×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	0	NA	4	NA
Bunch/Bundle	Private Grower Day 0 Risk	NA	7.4×10^{-8}	9.6×10^{-7}	1.5×10^{-6}	NA
	Private Grower Days < $1x10^{-6}$	NA	0	0	2	NA
	Com.. Farmworker Day 0 Risk	NA	2.2×10^{-7}	2.9×10^{-6}	4.4×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	0	5	8	NA
Low /Med. Field/Row Crops	Private Grower Day 0 Risk	NA	3.1×10^{-8}	4.7×10^{-7}	7.8×10^{-7}	NA
	Private Grower Days < $1x10^{-6}$	NA	0	0	0	NA
	Com.. Farmworker Day 0 Risk	NA	9.3×10^{-8}	1.4×10^{-6}	2.3×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	0	2	5	NA

Table 25: Summary of Carbaryl Cancer Postapplication Worker Risks						
Crop Group	Result Type	Exposure Descriptor (From Policy 003)				
		Very Low	Low	Medium	High	Very High
Tall Field/Row Crops	Private Grower Day 0 Risk	NA	1.2×10^{-7}	5.0×10^{-7}	1.2×10^{-6}	2.1×10^{-5}
	Private Grower Days < $1x10^{-6}$	NA	0	0	2	23
	Com.. Farmworker Day 0 Risk	NA	3.7×10^{-7}	1.5×10^{-6}	3.7×10^{-6}	8.5×10^{-5}
	Com.. Farmworker Days < $1x10^{-6}$	NA	0	3	10	31
Cut Flowers	Private Grower Day 0 Risk	NA	1.0×10^{-6}	1.7×10^{-6}	2.9×10^{-6}	NA
	Private Grower Days < $1x10^{-6}$	NA	0	3	6	NA
	Com.. Farmworker Day 0 Risk	NA	3.1×10^{-6}	5.0×10^{-6}	8.7×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	6	9	12	NA
Sugarcane	Private Grower Day 0 Risk	NA	NA	5.6×10^{-7}	1.1×10^{-6}	NA
	Private Grower Days < $1x10^{-6}$	NA	NA	0	1	NA
	Com.. Farmworker Day 0 Risk	NA	NA	1.7×10^{-6}	3.3×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	NA	3	6	NA
Decid. Fruit Trees	Private Grower Day 0 Risk	2.1×10^{-8}	2.1×10^{-7}	NA	6.3×10^{-7}	NA
	Private Grower Days < $1x10^{-6}$	0	0	NA	0	NA
	Com.. Farmworker Day 0 Risk	6.3×10^{-8}	6.3×10^{-7}	NA	1.9×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	0	0	NA	6	NA
Evergreen Fruit Trees	Private Grower Day 0 Risk	5.2×10^{-8}	5.2×10^{-7}	1.6×10^{-6}	NA	NA
	Private Grower Days < $1x10^{-6}$	0	0	5	NA	NA
	Com.. Farmworker Day 0 Risk	1.6×10^{-7}	1.6×10^{-6}	4.7×10^{-6}	NA	NA
	Com.. Farmworker Days < $1x10^{-6}$	0	5	16	NA	NA
Nut Trees	Private Grower Day 0 Risk	NA	1.7×10^{-7}	NA	8.7×10^{-7}	NA
	Private Grower Days < $1x10^{-6}$	NA	0	NA	0	NA
	Com.. Farmworker Day 0 Risk	NA	5.7×10^{-7}	NA	2.6×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	0	NA	10	NA
Turf/Sod	Private Grower Day 0 Risk	NA	8.1×10^{-8}	NA	2.7×10^{-6}	NA
	Private Grower Days < $1x10^{-6}$	NA	0	NA	2	NA
	Com.. Farmworker Day 0 Risk	NA	2.4×10^{-7}	NA	8.0×10^{-6}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	0	NA	4	NA

Table 25: Summary of Carbaryl Cancer Postapplication Worker Risks						
Crop Group	Result Type	Exposure Descriptor (From Policy 003)				
		Very Low	Low	Medium	High	Very High
Root Veg.	Private Grower Day 0 Risk	NA	1.2×10^{-7}	6.2×10^{-7}	1.0×10^{-6}	NA
	Private Grower Days < 1×10^{-6}	NA	0	0	0	NA
	Com.. Farmworker Day 0 Risk	NA	3.7×10^{-7}	1.9×10^{-6}	3.1×10^{-6}	NA
	Com.. Farmworker Days < 1×10^{-6}	NA	0	4	6	NA
Cucurbit Veg.	Private Grower Day 0 Risk	NA	2.1×10^{-7}	6.2×10^{-7}	1.0×10^{-6}	NA
	Private Grower Days < 1×10^{-6}	NA	0	0	0	NA
	Com.. Farmworker Day 0 Risk	NA	6.2×10^{-7}	1.9×10^{-6}	3.1×10^{-6}	NA
	Com.. Farmworker Days < 1×10^{-6}	NA	0	4	6	NA
Fruiting Veg.	Private Grower Day 0 Risk	NA	2.1×10^{-7}	2.9×10^{-7}	4.1×10^{-7}	NA
	Private Grower Days < 1×10^{-6}	NA	0	0	0	NA
	Com.. Farmworker Day 0 Risk	NA	6.2×10^{-7}	8.7×10^{-7}	1.2×10^{-6}	NA
	Com.. Farmworker Days < 1×10^{-6}	NA	0	0	1	NA
Brassica	Private Grower Day 0 Risk	NA	8.3×10^{-7}	1.7×10^{-6}	2.1×10^{-6}	NA
	Private Grower Days < 1×10^{-6}	NA	0	3	4	NA
	Com.. Farmworker Day 0 Risk	NA	2.5×10^{-6}	5.0×10^{-6}	6.2×10^{-6}	NA
	Com.. Farmworker Days < 1×10^{-6}	NA	5	9	10	NA
Leafy Veg.	Private Grower Day 0 Risk	NA	2.1×10^{-7}	6.2×10^{-7}	1.0×10^{-6}	NA
	Private Grower Days < 1×10^{-6}	NA	0	0	0	NA
	Com.. Farmworker Day 0 Risk	NA	6.2×10^{-7}	1.9×10^{-6}	3.1×10^{-6}	NA
	Com.. Farmworker Days < 1×10^{-6}	NA	0	4	6	NA
Stem/stalk Veg.	Private Grower Day 0 Risk	NA	2.2×10^{-7}	3.7×10^{-7}	7.4×10^{-7}	NA
	Private Grower Days < 1×10^{-6}	NA	0	0	0	NA
	Com.. Farmworker Day 0 Risk	NA	6.7×10^{-7}	1.1×10^{-6}	2.2×10^{-6}	NA
	Com.. Farmworker Days < 1×10^{-6}	NA	0	1	4	NA
Vine/trellis	Private Grower Day 0 Risk	NA	2.1×10^{-7}	4.1×10^{-7}	2.1×10^{-6}	4.1×10^{-6}
	Private Grower Days < 1×10^{-6}	NA	0	0	4	8
	Com.. Farmworker Day 0 Risk	NA	6.2×10^{-7}	1.2×10^{-6}	6.2×10^{-6}	1.2×10^{-5}
	Com.. Farmworker Days < 1×10^{-6}	NA	0	1	10	13

Table 25: Summary of Carbaryl Cancer Postapplication Worker Risks						
Crop Group	Result Type	Exposure Descriptor (From Policy 003)				
		Very Low	Low	Medium	High	Very High
Nursery/ Ornamentals	Private Grower Day 0 Risk	NA	4.5×10^{-8}	7.2×10^{-8}	1.7×10^{-7}	NA
	Private Grower Days < $1x10^{-6}$	NA	0	0	0	NA
	Com.. Farmworker Day 0 Risk	NA	1.4×10^{-7}	2.2×10^{-7}	5.0×10^{-7}	NA
	Com.. Farmworker Days < $1x10^{-6}$	NA	0	0	0	NA

7.3 Occupational Risk Characterization

Characterization of the occupational risks is included below for both handlers and for postapplication exposures.

Handlers: The occupational handler assessment for carbaryl is complex in that three different types of noncancer risk calculations were required based on the recently selected endpoints. The durations of exposure that were considered for noncancer toxicity were short-term (≤30 days), intermediate-term (30 days up to several months), and chronic (every working day). A complete array of calculations was completed for all identified exposure scenarios using the short- and intermediate-term endpoints because the Agency believes that carbaryl uses fit the criteria for both of these durations. The only calculations that were completed using the chronic endpoint were limited and those associated with the greenhouse and floriculture industries where these kinds of exposures may occur. Cancer risks were also calculated using a linear, low-dose extrapolation model (i.e., Q_1*) for both private growers (i.e., 10 application days per year) and for those who may more actively use carbaryl such as a commercial applicator (i.e., 30 application days per year). Cancer calculations were completed as well for every scenario that has been identified for both private growers and commercial applicators. For all of the different types of endpoints selected (except chronic where a limited number of calculations were completed), the Agency identified exposures that fit into 28 different scenarios which are defined based on the equipment used to make applications or the type of formulation used. Within each of these categories, different application rates and acres treated values were considered to evaluate the broad range of applications that may occur with each kind of equipment (e.g., a groundboom may be used for turf or agriculture). All totaled, 128 different crop/rate/acres combinations were considered within the 28 scenarios for the short- and intermediate-term toxicity categories plus 4 chronic crop/rate/acre combinations. The overall result is that 4 sets of 128 calculations each (516 total calculations) were completed for occupational carbaryl handlers. Finally, it should be noted that each calculation was completed at different levels of personal protection to allow for a more informed risk management decision. Even given the scope of the calculations that have already been completed, it is likely that there are some uses of carbaryl that have not been quantitatively addressed in this document either through lack of exposure data or other information and because carbaryl is such a widely used chemical. These scenarios will be addressed by the Agency when they are identified as carbaryl progresses through the reregistration process. Readers are also encouraged to evaluate novel scenarios by considering the range of estimates already completed as it is likely that many uses could be quantitatively assessed by reviewing those calculations as a wide array of chemical use combinations and equipment types have already been considered.

The data that were used in the carbaryl occupational handler risk assessment represent the best data and approaches that are currently available. While some of the data which have been used may not be of optimal quality, they represent the best available data for the scenario in question. In many cases, the Pesticide Handlers Exposure Database (PHED) was used to develop the unit exposure values. The quality of the data included in PHED vary widely from scenarios that meet guideline requirements for studies to others where a limited number of poor quality datapoints are available. The results for each scenario should be reviewed in the context of the quality of these data. In addition to PHED, the Agency used a number of studies to define unit exposure values. Generally, the quality of these studies is excellent. Most, except for the trigger sprayer data, are very recent and based on the newest analytical requirements and monitoring techniques. PHED unit exposure values represent a central tendency of the data (i.e., geometric mean, median or arithmetic mean depending upon the distribution of the data). As such, the values based on the recent studies also are measures of central tendency (e.g., the geometric means were selected from each study for assessment purposes in most cases). Along with the unit exposure values used in the assessment, other inputs include application rates and daily acres treated values. Selected application rates represent a range for each major market in which carbaryl is used including agriculture, turf (lawncare, golf courses, etc.), ornamentals, and for wide area applications such as mosquito control. Many application rates also represent maximum amounts that are allowed by the label for certain settings. Where available, average use rates were also used to provide for a more informed risk management decision. The application rates that were selected for use in the risk assessment were defined based on labels, information provided by the Aventis Crop Science at the September 24, 1998 SMART Meeting for carbaryl, and based on various analyses of carbaryl use patterns completed by the Agency's Biological and Economic Analysis Division. The other key input for completing handler risk assessments used for defining how much chemical can be used in a day is how much can be treated in a day which is generally expressed as the number of acres treated per day. The values that were used for this parameter represent the latest Agency thinking on this issue. In fact, the *Science Advisory Council For Exposure* recently updated the policy for these inputs (July 2000 Exposure SAC Policy 9: *Standard Values for Daily Acres Treated in Agriculture*). These most recent values have been used for the calculations.

In addition to the key sources of information considered above, there are many underlying factors that may impact the overall results of a risk assessment. For example, the protection factors used for adding additional levels of dermal and respiratory protection may impact the overall risk picture. The factors used in this assessment by the Agency are the ones that have been used for several years. Other such factors may include the fact that average application rates have been generally used to represent typical application rates to calculate ranges of risks when it is clear that the two values could differ greatly. The Agency has taken this approach because the data required to define typical application rates within each crop are generally unavailable. There are also exposure monitoring issues that should be considered. For example, in many cases the data included in PHED are based on the use of cotton gloves for hand exposure monitoring which are thought by many to overestimate exposure because they potentially retain residues more than human skin would over time (i.e., they may act like a sponge compared to the actual hand). A similar issue was noted with the carbaryl-specific dog grooming study that used the handwash approach to monitor exposure after shampooing several dogs. These intangible elements of the risk assessment reflect many of the hidden uncertainties associated with exposure data. The overall impacts of these uncertainties is hard to quantify. The factor to again consider is that the Agency used the best available data to complete the risk assessment for carbaryl.

In summary, the Agency believes that the risk values presented in this occupational assessment represent the highest quality results that could be produced given the exposure, use, and toxicology data that are available. Certainly risk managers and other interested parties should consider the quality of individual inputs when interpreting the results and make decisions accordingly. It is difficult to ascertain where on a distribution the values which have been calculated fall because the distributional data for exposure, application rates, acres treated and many other parameters are unrefined. The Agency does believe, however, that the risks represent conservative estimates of exposure because maximum application rates are coupled with large acreage estimates to define risk estimates that likely fall in the upper percentiles of the actual exposure distributions. Additionally, risk estimates are thought to be conservative even when measures of central tendency are combined because values that would be considered to be in the lower percentile aspect of any input parameter have not been used in the calculations.

Postapplication: Like the occupational handler risk assessment discussed above, the postapplication worker risk assessment for carbaryl is also complex in that three different types of noncancer risk calculations were required based on the recently selected endpoints along with cancer risk calculations using a linear, low-dose extrapolation model. For all of the different types of endpoints selected (except chronic where a limited number of calculations were completed), the Agency identified exposures that fit into 18 different crop groups which are defined essentially based on the nature of the crop where a work activity would take place. Within each of these crop groups, ranges of transfer coefficients were considered to reflect differences in exposures that would be associated with the variety of cultural practices that are required to produce the crop/product. All totaled, 54 different cultural practices were considered within the 18 crop groups for each toxicity category. The overall result is that 4 sets of 54 calculations each (216 plus a few chronic values) were completed for postapplication workers. Finally, it should be noted that each calculation was completed at different days after application to reflect residue dissipation over time in the environment and to allow for a more informed risk management decision. Even given the scope of the calculations that have already been completed, it is likely that there are some uses of carbaryl that have not been quantitatively addressed in this document either through lack of exposure data or other information and because carbaryl is such a widely used chemical. These scenarios will be addressed by the Agency when they are identified as carbaryl progresses through the reregistration process. Readers are also encouraged to evaluate novel scenarios by considering the range of estimates already completed as it is likely that many uses could be quantitatively assessed by reviewing existing calculations as a wide array of crop/activity combinations have already been considered.

The data that were used in the carbaryl postapplication worker risk assessment represent the best data and approaches that are currently available. The latest Agency transfer coefficient values have been used to complete this assessment including the recently submitted ARTF studies on greenhouse workers. Most of the values in the current Agency policy are based on the work of the Agricultural Reentry Task Force (ARTF) of which, Aventis Crop Science is a member. The current Agency policy is interim in nature but represents all of the data that have been submitted by the ARTF and evaluated by the Agency. The work of the ARTF is still ongoing so additional data may become available to refine the exposure estimates as more data are submitted to the Agency. Also, it is possible that there are exposure scenarios that have not been addressed by the Agency because the transfer coefficient model is not appropriate as there is little or no foliar contact associated with the activity. There are also potentially, partially mechanized activities that could lead to exposure where the Agency has no information. These will need to be carefully considered in the reregistration process. In addition to the exposure inputs for specific activities (i.e., transfer coefficients), the Agency used 4 carbaryl-specific

DFR (Dislodgeable Foliar Residue) dissipation studies and a single TTR (Turf Transferable Residue) study to calculate risks for all postapplication workers in every region in the country. It is standard practice for the Agency to use these kinds of studies in this manner but it is likely that additional crop- and region-specific data could be used to further refine the risk assessment. Several other key pieces of data and information were considered in the development of the postapplication risk values including use and usage information and exposure frequency in the cancer risk assessment. For many agricultural crops, the maximum application rate is low (e.g., 1.5 to 2 lb ai/acre) in many crops. As a result, postapplication risks were generally calculated at maximum rate levels because of the already inherent complexity of the assessment and because it is likely that results may not be extremely sensitive to changes in this value.

In addition to the key sources of information considered above, there are many underlying factors that may impact the overall results of a risk assessment. For example, subtle differences between activities in similar crops within each of the 18 agronomic groups considered in the assessment may not be accurately reflected in the current transfer coefficient values. The use of 4 DFR studies to represent all crops and all regions within the country could lead to results that do not reflect actual use practices and conditions in some parts of the country. Additionally, the exposure frequency values that were used for private growers and professional farmworkers tend to be supported by available data but could be refined if data on work patterns and regional carbaryl use becomes available. As with the handler assessment above, the intangible elements reflect many of the hidden uncertainties associated with exposure data. The overall impacts of these uncertainties is hard to quantify. The factor to again consider is that the Agency used the best available data to complete the risk assessment for carbaryl.

In summary, the Agency believes that the risk values presented in this postapplication assessment represent the highest quality results that could be produced given the exposure, use, and toxicology data that are available. Certainly risk managers and other interested parties should consider the quality of individual inputs when interpreting the results and make decisions accordingly. It is difficult to ascertain where on a distribution the values which have been calculated fall because the distributional data for exposure, residue dissipation and many other parameters are unrefined. The Agency does believe, however, that the risks represent conservative estimates of exposure because maximum application rates are used to define residue levels upon which the risk calculations are based. Additionally, risk estimates are thought to be conservative even when measures of central tendency (e.g., most transfer coefficients are thought to be central tendency) are used because values that would be considered to be in the lower percentile aspect of any input parameter have not been used in the calculations.

8.0 HUMAN AND DOMESTIC ANIMAL INCIDENT DATA REVIEW

Data on incidents of adverse reactions in humans exposed to carbaryl were evaluated from several sources, including OPP's Incident Data System, Poison Control Centers, California Department of Pesticide Regulation, National Pesticide Telecommunications Network and the open literature. The data from the Incident Data System indicated that a majority of cases from carbaryl exposure involved dermal reactions. A number of cases involved asthmatics and people who experienced hives and other allergic type reactions. According to California data, about half of the cases involved skin and eye effects in handlers. About a quarter of the skin reactions were due to workers that were exposed to residues on crops. Reports from the literature are very limited but tend to support the finding that carbaryl has irritant properties.

The Poison Control Center cases involving non-occupational adults and older children showed an increased risk in five of the six measures reported. These cases were almost twice as likely to require serious health care (hospitalization or treatment in a critical care unit) and were two and a half times more likely to experience major medical outcome (life-threatening effects or significant residual disability) as compared to other pesticides. This pattern of increased risk was not seen among occupational reports or in young children. This may mean careless handling by non-professionals is a particular hazard.

Five case reports suggested that carbaryl may be a cause of chronic neurological or psychological problems. Some of these effects appear to be consistent with those reported from organophosphate poisoning. However, unlike organophosphates, no controlled studies have been undertaken. If such effects occur as a result of over-exposure to carbaryl, they appear to be relatively rare. The effects reported among the five case reports are too inconsistent to draw any conclusions, but do suggest the need for further study.

Carbaryl appears capable of causing dermal and allergic type reactions. Data support the need for personal protective equipment and eye protection for handlers for field workers who may have extensive exposure to carbaryl. Labels for products should advise that carbaryl can cause sensitizing effects in some people.

Based on an evaluation of limited incident data on domestic animals in IDS, it is recommended that all labels for carbaryl products used on cats contain the age restriction stated in PR Notice 96-6 (should not be used in kittens less than 12 weeks of age).

A detailed discussion of the incident data is presented in Appendix 2.

9.0 DATA NEEDS

Toxicology data gaps

- 90-day inhalation study in rats with cholinesterase measurements

Product chemistry data gaps

- A review of the labels and supporting residue data indicate that several label amendments are required. Details are provided in the Product and Residue Chemistry Chapters (DP Barcode: D240989) dated November 14, 2000.

- The requirement for acceptable enforcement methods which determine residues of concern in plant and livestock commodities remains outstanding.

- The requirements for storage stability data are not satisfied for purposes of reregistration.

Additional data are required depicting the storage stability of carbaryl *per se* in an oilseed, processed commodities of an oily crop, and a dried fruit stored for up to 10 months. In addition, the registrant is relying on earlier magnitude of the residue studies that are not supported by the existing storage stability data; therefore, additional storage stability data are required. The required data must reflect storage intervals of 18 months for alfalfa commodities, 15 months for potatoes, 17 months for cottonseed, 22 months for wheat commodities, and 33 months for rangeland grass. In addition, if the registrant wishes to rely on the previously submitted sugar beet processing study, information pertaining to sample conditions and intervals for the study must be submitted.

- For the purpose of reregistration, the requirements for storage stability data for carbaryl residues in livestock commodities are partially satisfied. Additional information on the storage intervals prior to analysis for metabolite residues in the cattle feeding study is required.

- Separate tolerances on many commodities need to be reassigned concomitant with establishing tolerances for the appropriate crop group and subgroup. The recommended changes are summarized in Table C under "Tolerances Needed Under 40 CFR §180.169(a), crop group/subgroup tolerances" of the Product and Residue Chemistry Chapters.

- The data submitted are not adequate to support the use of granular (G) formulations of carbaryl on leafy vegetables. Residues of carbaryl found in leaf lettuce were not consistent. Both samples of lettuce from the 10% G treatment had substantially higher residues (37.01 and 47.22 ppm) than one of the samples treated with the FlC (23.25 ppm). Additionally, all residues were significantly above the current tolerance of 10 ppm and all residue data submitted in support of the tolerance in lettuce (<8.85 ppm). No explanation for the higher residues was given by the registrant. The registrant may elect to repeat the side by side trial on leaf lettuce again or submit a rationale for the results of the leaf lettuce study.

- Data are required depicting residues of carbaryl in/on grass forage harvested immediately (0-day) following the last of two applications of carbaryl (WP or FlC) at 1.5 lb ai/A to pasture. A total of 12 field trials are required in areas throughout the U.S.

- Adequate data are available to reassess the tolerances for residues of carbaryl in/on dried beans, cowpeas, lentils and peas with pods. These data support the establishment of crop subgroup tolerances for edible-podded legume vegetables (6A), and for dried, shelled pea and bean except soybean (6C). However, additional residue data are required if the registrant seeks tolerances for residues in/on succulent, shelled pea and bean commodities. A total of 12 tests, six tests each on a succulent, shelled cultivar of bean and garden pea, are required to support a tolerance for residues in/on the succulent, shelled pea and bean crop subgroup (6B). The registrant is referred to OPPTS GLN 860.1500 for the number and distribution of tests required.

- Adequate data are available to reassess the tolerance for wheat forage and straw. However, the Agency now considers wheat hay a significant RAC for feed purposes (OPPTS GLN 860.1000 Table 1.). A full set of 20 field trials as specified in OPPTS GLN 860.1500 are required depicting carbaryl residues in/on wheat hay. When all the field trials are complete, PHIs and tolerances for hay based on the field trial data should be proposed. Data on wheat hay will be translatable to proso millet hay.

- Adequate residue data are available on olives provided that use directions for olives are amended to remove the statement allowing the use of summer oil as an adjuvant. Alternatively, two additional field trials are required supporting the use of a carbaryl-summer oil tank mix.

- The registrant intends to support a tolerance for residues of carbaryl in/on imported pineapples (Aventis Crop Science personal communication with C. Olinger, 9/24/98 SMART meeting). Residue data are required depicting residues in/on pineapples following application of carbaryl at the maximum use rate and minimum PHI. Five trials must be submitted, three from Costa Rica and two from Mexico.

- Additional data are required depicting carbaryl residues in/on cotton gin byproducts derived from cotton treated at the maximum labeled rate and harvested 28 days after the final application using commercial equipment (stripper and mechanical picker). At least three field trials representing each type of harvesting (stripper and picker) are required.

- The registrant does not intend to support carbaryl uses on avocados, barley, maple sap, oats, rye, and sweet sorghum; however, IR-4 has indicated (Correspondence from K. Dorschner, IR-4 Project, 9/15/94) that they may fulfill the residue data requirements for some of these commodities. These data have not been submitted.

- The reregistration requirements for magnitude of the residue in livestock commodities are not fulfilled. Additional data are required to support dermal and poultry house uses.

Occupational/Residential Exposure Data Gaps

Residential Exposure

- For the postapplication risk assessments, there are no data on the amount of residues transferrable from treated pets to humans. Additional residue data on turf would help refine the hand-to-mouth and object-to-mouth toddler exposures.

Occupational Exposure

- For the occupational handler risk assessments, several exposure data gaps were identified, including: dust use for animal grooming and in agriculture; various specialized hand equipment application methods (e.g., powered backpack, power hand fogger, and tree injection); and nursery operations such as seedling dips.

- For <u>occupational postapplication</u> risk assessments, several data gaps exist, such as an incomplete dislodgeable foliar residue database and a lack of exposure data on partially mechanized cultural practices where there is a potential for exposure.

- There are also many kinds of mechanized activities that do not involve foliar contact that have not been addressed in this risk assessment. The scenarios include: transplanting many crops including in the ornamental and forestry industry; thinning some crops such as hops; some partially mechanized operations that also involve human contact (e.g., cotton harvesting where module builders and trampers are used); hand weeding some crops such as wheat; various operations with Christmas trees such as pruning or baling; and various operations with nut production such as sweeping for harvest.

APPENDIX **1**: Toxicology Profile

Appendix 1/Table 1: Toxicology Profile of Carbaryl

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100 90-Day oral toxicity rodents	N/A	
870.3150 90-Day oral toxicity in nonrodents	N/A	
870.3200 21/28-Day dermal toxicity with technical carbaryl	45630601(2002) acceptable/nonguideline 0, 20, 50, 100 mg/kg/day	systemic NOAEL = 20 mg/kg/day systemic LOAEL = 50 mg/kg/day based on decreased RBC cholinesterase in males and females and brain cholinesterase in males dermal NOAEL = 100 mg/kg/day dermal LOAEL not established
870.3200 21/28-Day dermal toxicity with Sevin® XLR Plus (44.82% a.i.)	45630602 (2002) unacceptable/nonguideline 0, 20, 50, 100 mcL/kg/day (0, 9.6, 24, 48 mg/kg/day)	systemic NOAEL = 50 mcL/kg/day (24 mg/kg/day) systemic LOAEL = 100 mcL/kg/day (48 mg/kg/day) based on decreased body weight gain dermal NOAEL = 100 mcL/kg/day (48 mg/kg/day) dermal LOAEL not established
870.3200 21/28-Day dermal toxicity with Sevin® 80S (80.07% a.i.)	45630603 (2002) unacceptable/nonguideline 0, 20, 50, 100 mg/kg/day	systemic NOAEL = 20 mg/kg/day systemic LOAEL = 50 mg/kg/day based on decreased RBC cholinesterase in males and females dermal NOAEL = 100 mg/kg/day dermal LOAEL not established
870.3250 90-Day dermal toxicity	N/A	
870.3465 90-Day inhalation toxicity	N/A	
870.3700a Prenatal developmental in rats	44732901 (1998) acceptable/guideline 0, 1, 4, 30 mg/kg/day (oral gavage)	Maternal NOAEL = 4 mg/kg/day LOAEL = 30 mg/kg/day based on clinical signs, decreased body weight gain (BWG) and food consumption Developmental NOAEL = 4 mg/kg/day LOAEL = 30 mg/kg/day based on decreased fetal body weight and incomplete ossification of multiple bones
870.3700b Prenatal developmental in rabbits	44904202 (1999) Acceptable/guideline 0, 5, 50, 150 mg/kg/day (oral gavage)	Maternal NOAEL = 5 mg/kg/day LOAEL = 50 mg/kg/day based on decreased BWG and plasma cholinesterase inhibition (ChEI) Developmental NOAEL = 50 mg/kg/day LOAEL = 150 mg/kg/day based on decreased fetal weight

Appendix 1/Table 1: Toxicology Profile of Carbaryl		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3800 Reproduction and fertility effects	45448101 (2001) acceptable/guideline 0, 75, 300, 1500 ppm (4.67, 31.34, and 92.43 mg/kg/day for F_0 males; 0, 5.56, 36.32, and 110.78 mg/kg/day for F_0 females; 0, 5.79, 23.49, and 124.33 mg/kg/day for F_1 males; and 0, 6.41, 26.91, and 135.54 mg/kg/day for F_1 females averaged over the premating period)	Parental NOAEL = 300 ppm (23.49-31.34 mg/kg/day for males and 26.91-36.32 mg/kg/day for females) Parental LOAEL = 1500 ppm (92.43-124.33 mg/kg/day for males and 110.78-135.54 mg/kg/day for females) based on decreased body weight, weight gain, and feed consumption Reproductive toxicity NOAEL is ≥1500 ppm (92.43-124.33 mg/kg/day for males and 110.78-135.54 mg/kg/day for females) Reproductive toxicity LOAEL not be established Offspring NOAEL = 75 ppm (4.67-5.79 mg/kg/day for males and 5.56-6.41 mg/kg/day for females). Offspring LOAEL = 300 ppm (23.49-31.34 mg/kg/day for males and 26.91-36.32 mg/kg/day for females) based on increased numbers of F_2 pups with no milk in the stomach and decreased pup survival.
870.4100a Chronic toxicity in rodents	N/A	
870.4100b Chronic toxicity in dogs	40166701 (1987) 0, 125, 400, 1250 ppm (0, 3.1, 10, 31.3 mg/kg/day) 42022801 (1991) 0, 20, 45, 125 ppm (5 weeks) (M: 0, 0.59, 1.43, 3.83; F: 0, 0,64, 1.54, 4.11 mg/kg/day) Together, the studies are Acceptable/guideline	MRID 40166701: NOAEL = not established in females LOAEL = 125 ppm based based on plasma and brain ChEI MRID 42022801: NOAEL = 45 ppm in males LOAEL = 125 ppm in males based on plasma ChEI
870.4200 Carcinogenicity in mice	42786901 (1993) Acceptable/guideline 0, 100, 1000 or 8000 ppm (M:0, 14.73, 145.99, 1248.93 mg/kg/day; F: 0, 18.11, 180.86, 1440.62)	systemic LOAEL = 1000 ppm based on increased intracytoplasmic droplets in bladder in males and females, chronic progressive nephropathy in males; NOAEL = 100 ppm RBC ChEI LOAEL for males = 1000 ppm , for females = 8000 ppm; NOAEL = 100 ppm for males, 1000 ppm for females plasma ChEI for males and females LOAEL > 8000 ppm; NOAEL ≥ 8000 ppm brain ChEI for males and females LOAEL = 8000 ppm; NOAEL = 1000 ppm increase in vascular tumors in all treated males and in females at 8000 ppm increase in adenomas, multiple adenomas, carcinomas of kidney in males at 8000 ppm increase in hepatic neoplasms (adenomas, carcinomas, one hepatoblastoma) in females at 8000 ppm

Appendix 1/Table 1: Toxicology Profile of Carbaryl

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.4300 Chronic Toxicity/ Carcinogenicity in rats	42918801 (1993) Acceptable/guideline 0, 250, 1500 & 7500 ppm (M: 0, 10, 60.2, 349.5 mg/kg/day; F: 0, 12.6, 78.6, 484.6 mg/kg/day)	systemic LOAEL = 1500 ppm in females based on decreased BW and BWG; 7500 ppm in males based on increased clinical signs, decreased BW, BWG and food consumption, increase in cataracts, clinical pathology changes, organ weight changes, nonneoplastic changes; NOAEL = 250 ppm in females and 1500 ppm in males plasma ChEI LOAEL = 7500 ppm in males and females; NOAEL = 1500 ppm RBC ChEI LOAEL = 1500 ppm in males and females; NOEL = 250 ppm brain ChEI LOAEL = 7500 ppm in males and females; NOEL = 1500 ppm at 7500 ppm, increase in liver adenomas in females, increase in benign transitional cell papillomas and transitional cell carcinomas in males and females, transitional cell carcinoma in kidney of one male, increase in benign thyroid follicular cell adenomas in males, follicular cell carcinoma in one male
Bacterial reverse mutation test 870.5100	41370303 (1989) Acceptable/guideline 5-1000 ug/plate	No evidence of mutagenicity in strains TA1535, TA 1537, TA1538, TA98 and TA100 with and without metabolic activation
In vitro mammalian chromosome aberration test (Chinese hamster ovary cells) 870.5385	41370304 (1989) Acceptable/guideline without S9 activation: 5-100 ug/mL, harvest at 20 hrs.; with S9 activation: 25-300 ug/mL, harvest at 30 hrs	Increase in chromosome aberrations with S9 activation
In vitro mammalian chromosome aberration test 870.5385	41370302; 41420201 (1989) Unacceptable/guideline S9 activation: 1-300 ug/mL in 3 trials; without S9 activation: 1-300 ug/mL in 2 trials	Results provide no clear indication of a mutagenic response, however study had several deficiencies
Mammalian erythrocyte micronucleus test 870. 5395	44069301 (1996) Unacceptable/guideline single oral gavage dose of 50, 100, 200 mg/kg	Carbaryl did not induce a clastogenic or aneugenic effect, however there was no convincing evidence that MTD was achieved
Unscheduled DNA synthesis 870.5550	41370301; 41810601 (1989) Acceptable/guideline 0.5 - 25.0 ug/mL	Negative
870.6200a Acute neurotoxicity screening battery in rats	MRID: 43845201-43845204 (1995) Acceptable/guideline 0, 10, 50, 125 mg/kg (oral gavage) Separate study for ChEI: 0, 10, 30, 50 mg/kg; ChEI done 1, 8, 24, 48 hrs post-dosing	Systemic LOAEL = 10 mg/kg based on decreased RBC, plasma, blood, brain ChEI; NOAEL < 10 mg/kg

Appendix 1/Table 1: Toxicology Profile of Carbaryl

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.6200b Subchronic neurotoxicity screening battery in rats	MRID: 44122601 (1996) Acceptable/guideline 0, 1, 10, 30 mg/kg/day (oral gavage)	LOAEL for neurotoxicity = 10 mg/kg/day based on increased FOB changes; NOAEL = 1 mg/kg/day LOAEL for ChEI = 10 mg/kg/day based on decreased plasma, blood, RBC, brain ChEI; NOAEL = 1 mg/kg/day
870.6300 Developmental neurotoxicity in rats	44393701 (1997) Acceptable/guideline 0, 0.1, 1.0, 10 mg/kg (oral gavage)	**Maternal** NOAEL = 1.0 mg/kg/day LOAEL = 10 mg/kg/day based on decreased BWG; FOB changes; RBC, plasma, whole blood, brain ChEI **Offspring** tentative NOAEL = 1.0 mg/kg/day tentative LOAEL = 10 mg/kg/day based on alterations in morphometric measurements (measurements were not done at lower doses)
870.7485 Metabolism and pharmacokinetics in rats	43332101 (1994) Acceptable/guideline 1 mg/kg (single and repeated oral doses; intravenous dose) and 50 mg/kg (single oral dose)	Absorption was complete at all doses. At 168 hrs., post-dose, negligible percentages of dose in any tissues. Kidney and blood contained highest concentrations of radioactivity. Excretion mostly through urine. A metabolic scheme with conjugated and non-conjugated metabolites was proposed.
870.7485 Metabolism and pharmacokinetics in rats	44402501 (1997) Acceptable/nonguideline 50 mg/kg (single oral radiolabeled dose); daily oral radiolabeled dose of 2 mg/kg for 7 days followed by 83 daily unlabeled doses of 0, 250, 1500 or 7500 ppm; males only	In all dosing regimens, urinary and fecal excretion was 93-103% of administered dose and tissue levels of radioactivity were minimal at 168 hrs. post-dosing. Two major metabolites in tissues at 6 hrs. post-dosing were naphthyl sulfate and naphthyl glucuronide, however quantitation was not possible. A total of 23 and 20 components were identified in the urine and feces, respectively. The sulfate conjugation pathway appears to be saturable following a 83-day feeding at 7500 ppm. BW and food consumption were decreased at 7500 ppm. Increases in kidney, spleen and thyroid weights were observed at 1500 and 7500 ppm. Non-neoplastic changes in liver, thyroids and kidneys were observed at 7500 ppm.
870.7600 Dermal penetration in rats	43552901 (1995) 43.9% a.i. Acceptable 35.6, 403, 3450 ug/cm^2	% absorbed at 10 hrs.: 12.7, 7.44 and 1.93 at 35.6, 403 and 3450 ug/cm^2, respectively
870.7600 Dermal penetration in rats	43339701 (1994) 80.1% a.i. Acceptable 63, 626, 3410 ug/cm^2	% absorbed at 10 hrs: 8.90, 0.62 and 0.48 at 63, 626 and 3410 ug/cm^2, respectively
Special studies in mice	43282201 (1994) Acceptable/nonguideline male mice: single radiolabeled dose of 75 mg/kg; pretreatment with 8000 ppm unlabeled carbaryl for 2 wks., then single radiolabeled dose of 75 mg/kg	Negative for DNA binding in liver

Appendix 1/Table 1: Toxicology Profile of Carbaryl		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
Special studies in mice	43832601 (1994) Acceptable/nonguideline continuation of MRID 43282201	in liver from mice treated at 8000 ppm, increase in microsomal protein, cytochrome P450, ethoxyresorufin O-deethylase, pentoxyresorufin O-depentylase, and testosterone hydrolases indicates phenobarbital type of induction of metabolizing enzymes
Special study in mice	45281801, 45281802, 45236603 (1998-1999) Acceptable/nonguideline 0, 10, 30, 100, 300, 1000 and 4000 ppm (0, 1.8, 5.2, 17.5, 51.2, 164.5 and 716.6 mg/kg/day)	There was no evidence of neoplastic or preneoplastic changes in vascular tissue in heterozygous p53-deficient male mice treated with carbaryl for six months.

N/A Not Available

APPENDIX **2**: Incident Review

Conclusions/Recommendations Based on Incident Review

Data on incidents of adverse reactions in humans exposed to carbaryl were evaluated from several sources, including OPP's Incident Data System, Poison Control Centers, California Department of Pesticide Regulation, National Pesticide Telecommunications Network and the open literature. The data from the Incident Data System indicated that a majority of cases from carbaryl exposure involved dermal reactions. A number of cases involved asthmatics and people who experienced hives and other allergic type reactions. According to California data, about half of the cases involved skin and eye effects in handlers. About a quarter of the skin reactions were due to workers that were exposed to residues on crops. Reports from the literature are very limited but tend to support the finding that carbaryl has irritant properties.

The Poison Control Center cases involving non-occupational adults and older children showed an increased risk in five of the six measures reported. These cases were almost twice as likely to require serious health care (hospitalization or treatment in a critical care unit) and were two and a half times more likely to experience major medical outcome (life-threatening effects or significant residual disability) as compared to other pesticides. This pattern of increased risk was not seen among occupational reports or in young children. This may mean careless handling by non-professionals is a particular hazard.

Five case reports suggested that carbaryl may be a cause of chronic neurological or psychological problems. Some of these effects appear to be consistent with those reported from organophosphate poisoning. However, unlike organophosphates, no controlled studies have been undertaken. If such effects occur as a result of over-exposure to carbaryl, they appear to be relatively rare. The effects reported among the five case reports are too inconsistent to draw any conclusions, but do suggest the need for further study.

Carbaryl appears capable of causing dermal and allergic type reactions. Data support the need for personal protective equipment and eye protection for handlers for field workers who may have extensive exposure to carbaryl. Labels for products should advise that carbaryl can cause sensitizing effects in some people.

Based on an evaluation of limited incident data on domestic animals in IDS, it is recommended that all labels for carbaryl products used on cats contain the age restriction stated in PR Notice 96-6 (should not be used in kittens less than 12 weeks of age).

A detailed discussion of the incident data is presented below.

Human Incident Data Review

A review of the human incident data on carbaryl was prepared by Dr. Jerome Blondell and Ms. Monica Spann (D267127 dated July 17, 2000).

The following data bases were consulted for the poisoning incident data on the active ingredient Carbaryl (PC Code:056801):

1) OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.

2) Poison Control Centers - as the result of a data purchase by EPA, OPP received Poison Control Center data covering the years 1993 through 1998 for all pesticides. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 65-70 centers at hospitals and universities.

3) California Department of Pesticide Regulation - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides.

4) National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991 and 1995-1999 has been prepared for the categories human incidents, animal incidents, calls for information, and others.

Incident Data System

There were approximately 500 reports in IDS concerning exposure of humans to carbaryl. At least 380 cases were considered minor (minimal symptoms with no residual disability) and were not included in the review. The most frequently reported symptoms were of a dermatological nature, either dermal irritation or possibly a dermal manifestation of an allergic response (e.g., hives, welts, rash, etc.). Clinical signs or symptoms less frequently reported were nausea, vomiting, diarrhea, respiratory irritation and difficulty breathing. Most of the incidents were associated with dermal exposure; however, a few resulted after inhalation of the product. There was one report of an attempted suicide. In 1993, a 21-year old man ingested about 75 ml of Beetle Bait (21.3% carbaryl, Registration Number 869-134). No information on the symptoms or outcome of the case were provided. There was also one death. In 1996, a woman with a history of chronic asthma experienced shock and severe respiratory distress after she used Mycodex Pet Shampoo (0.5% carbaryl, Registration Number 2097-8) on her dog. She was hospitalized but went into a coma and died five days later (IDS 3694-1).

Poison Control Center (PCC) Data - 1993 through 1998

The PCC data base for 1993 through 1998 contained 174 cases involving occupational exposures in adults and older children (outcome determined in 90 cases), 3033 nonoccupational exposures in adults and older children (outcome determined in 1351 cases) and 2147 exposures in children under the age of six (outcome determined in 1248 cases). Cases involving exposures to multiple products were excluded. The data from cases in which the outcome was determined were compared to all other pesticides using six measures: percent with symptoms, percent with moderate or more severe outcome, percent with life-threatening or fatal outcome, percent of exposed cases seen in a health care facility, percent hospitalized and percent seen in an intensive care facility.

For occupational cases, carbaryl appears to be somewhat less hazardous than all pesticides combined, as determined by five of the six measures reported. Cases involving non-occupational adults and older children showed an increased risk in five of the six measures reported. In particular these non-occupational cases were nearly twice as likely to require serious health care (hospitalization or treatment in a critical care unit) and were 2.5 times more likely to experience major medical outcome (life-threatening effects or significant residual disability). These data suggest that some consumers are using this chemical in a careless manner. For cases involving children under six years of age, carbaryl has a similar hazard profile to all other pesticides.

California Data - 1982 through 1996

Detailed descriptions of 226 cases submitted to the California Pesticide Illness Surveillance Program (1982-1996) were reviewed. In 90 of these cases, carbaryl was used alone or was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. Carbaryl ranked 37th as a cause of systemic poisoning in California. The number of reports from California declined by over half from the first five years of the reporting period (1982-1986) to the last five years (1992-1996). It is difficult to determine whether some of this decline might be related to a decrease in usage because the method of collecting use information changed after 1989. Of the 90 persons reported to have illnesses, a total of 43 (48%) had systemic illnesses, 20 (22%) had eye irritation, 21 (23%) had skin irritation, 1(1%) had respiratory illness and 5 (6%) had a combination of effects. A total of 26 workers were disabled (took time off work, 1 for more than 10 days) as the result of carbaryl exposure. Seven required hospitalization (1-5 days). Applicators were associated with the majority of the exposures. Clinical signs/symptoms in these workers included nausea, vomiting, skin rashes, sore throat, lip swelling, chemical conjunctivitis, dizziness, eye irritation, contact dermatitis, blurry vision, chest pains, and several other symptoms.

National Pesticide Telecommunications Network

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, carbaryl was ranked 5th with 503 incidents in humans reported and 85 incidents in animals (mostly pets). For the years 1995 through 1998, carbaryl's rank ranged from 7th to 12th with 110 incidents in humans reported and 26 incidents in animals. Most of the decline in reported human cases from the earlier time period is due to the reduced level of incident reporting overall. However, even taking this into account, there does appear to be some reduction in carbaryl incidents which is also reflected in the lower rankings reported for the later years (1995-1998).

Literature Summary

Thirteen epidemiological studies/case reports from the open literature were reviewed. Five case reports suggested that carbaryl may cause long-term neurological or psychologicalproblems.[12,13,14,15,16] Two of these cases involved attempted suicides in which large doses of carbaryl-containing products were ingested. Some of the effects from carbaryl exposure are consistent with those reported from organophosphate poisoning. However, no controlled studies have been conducted. If such effects occur as a result of carbaryl over-exposure, they appear to be relatively rare. The effects observed in the case reports are too inconsistent to draw any conclusions, but do suggest the need for further study.

Other literature articles concerned epidemiology studies to evaluate the effects of pesticides on reproduction. In the 1979 Ontario Farm Family Study by Savitz *et al*[17], the effects of activities and specific pesticides on male farmer's fertility were considered. The results suggested that thiocarbamates, carbaryl and other pesticides were most strongly associated with miscarriage. The adjusted odds ratio for carbaryl used on crops was 2.1 with a 95 percent confidence interval of 1.1 to 4.1 (borderline significance). Use of carbaryl in the yard was not associated with a significantly increased risk of miscarriage and carbaryl was not a significant risk factor for preterm delivery or small for gestational age births. In a 1979 study of male workers who produced and packaged carbaryl, Whorton *et al*[18] concluded that there was no evidence of sperm count suppression resulting from exposure to the chemical. Whorton et al. (1979) and Wyrobek et al[19] (1981) used the same cohort in their studies to determine the effects on fertility by checking for infertile marriages and by measuring sperm counts and serum gonadotropins. The carbaryl-exposed group included nearly three times as many oligospermic men as the control group. Wyrobek et al. (1981) concluded there was a non-dose related, significant elevation in sperm head abnormalities compared to controls, that may not be reversible. Both of the studies had low participation rates, relied on self-reporting of exposure levels, and used less than ideal control groups.

---

[12]Branch RA, Jacqz E (1986). Is carbaryl as safe as its reputation? Does it have a potential for causing chronic neurotoxicity in humans?. The American Journal of Medicine 80(4): 659-664.

[13]Brewer B (2000). A rare cause of acute confusional state (Letter to the Editor). Journal of Accidental Emergency Medicine 17(1): 77.

[14]Devinsky O, Kernan J, Bear DM (1992). Aggressive behavior following exposure to cholinesterase inhibitors. Journal of Neuropsychiatry 4(2): 189-194.

[15]Dickoff DJ, Gerber O, Turovsky Z (1987). Delayed neurotoxicity after ingestion of carbamate pesticide. Neurology 37(7): 1229-1231.

[16]Wiener PK, Young RC (1995). Late-onset psychotic depression associated with carbaryl exposure. American Journal of Psychiatry152(4):646-647.

[17]Savitz DA, Arbuckle T, Kaczor D, Curtis KM. (1997). Male pesticide exposure and pregnancy outcome. American Journal of Epidemiology 146(12): 1025-1036.

[18]Whorton DM, Avashia BH, Hull EQ. (1979). Testicular function among carbaryl-exposed employees. Journal of Toxicology and Environmental Health 5:929-941.

[19] Wyrobek AJ, Watchmaker G, Gordon L, Wong K, Moore D 2d, Whorton D (1981). Sperm shape abnormalities in carbaryl-exposed employees. Environmental Health Perspectives 40:255-265.

There were also two studies assessing carbaryl's potential to induce an allergic reaction. Senthilselvan et al. (1992)[20] reported on the association between self-reported asthma and pesticide use in 1,939 farmers. The prevalence of asthma was significantly associated with the use of carbamate insecticides regardless of age, smoking pack-years, and nasal allergic reactions. The authors concluded that the possibility of exposure to agriculture chemicals could be related to lung dysfunction in exposed farmers.

Sharma and Kaur (1990)[21] reported on 30 farmers that had contact dermatitis after using pesticides for several years. The farmers included 25 males and 5 females, between the ages of 28 and 70 years old. Patch testing was conducted on the upper back and readings were taken on the second, third, and seventh day. Allergic reactions to one or more pesticides were seen in 11 patients. One patient was sensitive to carbaryl and two patients to 3 each (2,4-D, thiram, carbaryl; pendimethalin, methyl parathion and carbofuran). Carbamates, including carbaryl, were the most frequent sensitizers. Allergic reactions did not occur in the twenty controls included in the study.

Unpublished Epidemiology Study

Rhone-Poulenc submitted an epidemiologic study of plant workers exposed to carbaryl titled "Standardized Mortality Ratio Analysis of Employees Exposed to Carbaryl at the Rhone-Poulenc Institute, West Virginia Plant", which was reviewed by Dr. Jerome Blondell (DP Barcode D194815). The results were part of a ten year vital status update undertaken by the National Institute of Occupational Safety and Health. The study included all individuals who were first hired between 1960 (when the production of carbaryl started) and through 1978. The vital status of all workers was determined through 1988 using the National Death Index.

A total of 522 employees were identified as belonging to either the production, packing/distribution, or maintenance facilities. Follow-up through 1988 showed 25 deaths, including nine due to cancer. Significantly less deaths (50%) were seen compared to the number expected. No category of death resulted in a statistically significant excess. Those categories that exhibited an excess (greater than the number of expected cases) were usually based on a single reported death with very wide confidence intervals. For brain cancer, there were two deaths (0.5 expected), but they had different histologic origin which reduces the likelihood that they were due to the same exposure. HED concluded that the epidemiologic study does not add significant new information concerning adverse health effects of carbaryl. The sample of workers was too small and the period of follow up to too short to permit definitive conclusions.

[20] Senthilselvan A, McDuffie HH, Dosman JA. 1992. Association of asthma with use of pesticides. Results of a cross-sectional survey of farmers. Am Rev Respir Dis 146(4): 884-887.

[21] Sharma VK, Kaur S. 1990. Contact sensitization by pesticides in farmers. Contact Dermatitis 23: 77-80.

Domestic Animal Incident Review

The domestic animal incident review was prepared by Dr. Virginia Dobozy (D266621 dated June 12, 2000). There are approximately 69 active products containing carbaryl with use sites for dogs and cats in OPP's Reference File System (REFS). The majority of the products are 5-10% lawn and garden dusts, which may be registered for use on animal bedding and thus are included in the REFS search. Most of the powders for intentional application to dogs and cats for flea and tick control also contain 5-10% carbaryl, some in combination with pyrethrins and synergists. However, two products contain 12.5% carbaryl in combination with pyrethrins. Three products contain carbaryl (10-12.5%) in combination with 0.25% methoxylchlor. There is one shampoo which contains 0.5% carbaryl, two flea collars with either 9.5% (cats) or 17% (dogs) carbaryl and a dip for dogs with 60% carbaryl. In general, the use of powders, dips and sprays for flea and tick control in dogs and cats has been replaced within the last five years with oral (FDA regulated) or spot-on formulations. As there are no spot-on carbaryl preparations, it can be assumed that the use of this chemical for flea and tick control has declined.

There are 213 reports in IDS for carbaryl for domestic animals from 1991 to May, 2000. Only those incidents from 1998 (most recent year with complete data) were reviewed in order to provide an evaluation of current adverse reports in domestic animals. In 1998, there were 35 incidents in IDS involving 23 dogs, 9 cats and 1 pig. One incident involved two dogs and in three incidents, the species was not identified. Only two incidents involved products registered for use on dogs and cats. In one, an 8 week-old kitten treated with Zodiac Flea and Tick Powder for Dogs developed vomiting and anorexia and died the next day. In the other, a dog was reported to have had a reaction to a shampoo with carbaryl; no other data were provided. The majority of the remaining incidents involved products containing a 5% carbaryl dust or a molluscicide which contains 2% metaldehyde and 5% carbaryl. A wide variety of clinical signs were reported. Most of the incidents were evaluated and classified as to causality (doubtful, low, moderate or high suspicion) by the ASPCA/National Animal Poison Control Center. All were classified as doubtful or low suspicion. A summary review of incidents for a 5% carbaryl powder from one registrant, along with the one report from 1998, provided some evidence that young kittens (<12 weeks) may be susceptible to adverse reactions to carbaryl. It is recommended that all labels for carbaryl products used on cats contain the age restriction stated in PR Notice 96-6 (should not be used in kittens less than 12 weeks of age).